IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

SECURITY NATIONAL BANK, as Conservator for JMK, a minor child,	No. C11-4017-MWB
Plaintiff,	Sioux City, Iowa January 13, 2014
vs.	8 a.m.
ABBOTT LABORATORIES,	Volume 6 of 10
Defendant.	

TRANSCRIPT OF TRIAL
BEFORE THE HONORABLE MARK W. BENNETT
UNITED STATES DISTRICT JUDGE, and a jury.

APPEARANCES:

For the Plaintiff:	AMANDA BRANDY VAN WYHE, ESQ. TIMOTHY S. BOTTARO, ESQ. Vriezelaar, Tigges, Edgington, Bottaro, Boden & Ross 613 Pierce Street Sioux City, IA 51102 STEPHEN C. RATHKE, ESQ. ROBERT J. KING, ESQ. Lommen, Abdo, Cole, King & Stageberg 2000 IDS Center 80 South Eighth Street Minneapolis, MN 55402
For the Defendant:	JOHN C. GRAY, ESQ. Heidman Law Firm 1128 Historic 4th Street Sioux City, IA 51102 DANIEL E. REIDY, ESQ. JUNE K. GHEZZI, ESQ. GABRIEL H. SCANNAPIECO, ESQ. KATHRYN L. DORE, ESQ. Jones Day Suite 3500 77 West Wacker Drive Chicago, IL 60601
Also present:	Louise Deitloff Daniel Morrison
Court Reporter:	Shelly Semmler, RMR, CRR 320 Sixth Street Sioux City, IA 51101 (712) 233-3846

(Proceedings reconvened outside the presence of the jury.)

THE COURT: Okay. Could we get started on a few matters this morning? I understand that the plaintiff thinks they may rest between like 9:30 and 10 this morning?

MR. RATHKE: Yes, Your Honor.

THE COURT: Okay. How extensive is your Rule 50 motion going to be? Are you going to go -- I mean, I haven't granted one in 20 years. I'm not going to grant one in this case I can tell you right now, so I know you want to make -- it depends on how extensive of a record you want to be will dictate when I will have you do it so . . .

MR. REIDY: Judge, I think we'll file a one-page piece of paper referring to our summary judgment argument and call it a day.

THE COURT: Okay. So you don't actually want to make any oral motion?

MR. REIDY: I don't want to take up the Court's time.

THE COURT: Okay.

MR. REIDY: Unless the Court wants to hear from us. My sense is that that would be taking up time that doesn't matter.

THE COURT: Yeah, I appreciate that, but I don't want you to have waived it in any way, so I'm a little bit worried you might have to -- why don't we do this. I mean, we can do it

a couple of different ways. If it's just going to be very short like we reurge all the arguments in our summary judgment motion and add a couple things, if we can do it in like five minutes or less, we could do it on the first break. Or what I usually do is -- but only if it's going to be a little more extensive, we'll make a record now that whenever you make -- I keep thinking Rule 29 motion because we do so many criminal cases more than civil. It's a Rule 50 motion for judgment as a matter of law.

MR. REIDY: Rule 50.

THE COURT: When you make your Rule 50 motion, why don't we do it tomorrow morning, but we'll make a record now that it will be deemed having been given at the close of the plaintiff's case and that you're not waiving anything by accommodating the schedule by making it tomorrow morning outside the presence of the jury, and I'm going to do that for a couple reasons. I don't want it to eat up into your very limited break, and I don't want to take the time when the plaintiff rests to send the jury out. I just want to start in on the defendant's case.

MR. REIDY: That'd be fine, Judge.

THE COURT: And you can file anything in writing you want, and it will be deemed having been submitted at the close of the plaintiff's case.

MR. REIDY: We'll give your staff something this

morning, Judge, and we'll just have it -- what we've done, Judge, is just reinvoked our causation expert arguments. I don't actually believe that I need to make a record. I think Your Honor understands our arguments. The only difference is that Your Honor has now seen their experts.

THE COURT: Yes.

MR. REIDY: And so we expect that Your Honor would be able to understand the arguments that we would make which is that just as we predicted, you know, based on their depositions. So as far as we're concerned, we'll file that this morning, and then Your Honor does not have to set aside a time for argument.

THE COURT: Okay.

MR. REIDY: Unless you want to hear from us.

THE COURT: No. I appreciate that, Mr. Reidy, and that's fine. That's a fine way to proceed with it.

You know, I was thinking about this case over the weekend which is always a mistake, but I've thought there was an evidentiary problem. I thought I had admitted some of the underlying studies, but I actually hadn't admitted those. They were never even offered -- well, you tried to offer one as an exhibit, and I denied it. So it must have been -- must have had it marked.

But I thought I had -- in the pretrial order because we went through so many iterations of the exhibit list, it was a little bit confusing, and maybe I was thinking about another

case or about one of the earlier exhibit lists. But I thought you had a number of the studies on it that the experts had relied on. They're hearsay, but they can rely on it. We've been through that. But you don't so -- and they're not admissible as substantive evidence. I thought I had inadvertently admitted some, so I was just going to unadmit them because the jury really hasn't seen them other than to the extent that they were on slides which were demonstrative.

But when I was reviewing the witness list this morning, I don't recall that any of the studies were being offered by either party. So am I correct on that, that nobody's tried to offer the underlying studies?

MR. REIDY: I believe that's right, Your Honor.

THE COURT: Okay. Thank you.

MR. RATHKE: I think the exhibit that you have in mind is an e-mail from Anna Bowen to somebody in Virginia that came up during the Jason testimony, and you did not admit that.

THE COURT: Okay. Moving on to the next matter, I think -- is the defense calling a video conference witness on Thursday that we're going to do by video?

MR. REIDY: Judge, I think that may be on Tuesday rather than Thursday because of the schedule of the witness.

THE COURT: Okay. And do you have a time on Tuesday?

MR. REIDY: If you can give us maybe until the first break to reconnoiter --

THE COURT: Sure, sure.

MR. REIDY: -- at the end of the first break, we'll give the Court a time.

THE COURT: And I think the reason is our tech people want it because I think they want to try and do a -- we always make a connection to see that everything's working properly.

MR. REIDY: We'll try -- we'll get --

THE COURT: But are you leaving today, Dave?

MR. JONES: No, I'll probably stay around. But we have to make a bridge call for this because it's an outside source, so we have to have a time to pull up bridge and make that connection, and then they'll connect into the bridge, so we kind of need a roundabout area.

THE COURT: Okay. So maybe you all can confer and confer with your witness and just get us a time.

MR. REIDY: We'll do that, Judge.

THE COURT: Great. Okay. And were we taking a witness out of order this morning? Wasn't there some talk about a defense witness that was going -- or is that the one we're talking about that we're doing on Tuesday now?

MS. GHEZZI: No, no, Your Honor, you're correct. But based on our conversations over the weekend, if the plaintiff rests at 9:30 or 10, we're going to take Dr. Shulman. Dr. Shulman is the one who has to get on and get off today because of his wife.

THE COURT: Okay. Okay. Great.

MS. GHEZZI: Thank you.

THE COURT: Thank you. Anything else on the parties' agenda?

Oh, you raised that issue -- I don't think the defense has responded to it yet -- with regard to the photographs that were -- and the testimony of Summer Johnson that were basically -- that were alleged to be foundation for the expert that you deposed on Friday, something like that?

MR. RATHKE: Your Honor, just to give it a name, the bedbug evidence came in on Summer Johnson, and the Court gave a limited instruction. After deposing Dr. Olson, it does not appear that any of all -- any of that was of any importance to him. So what we would request is that the Court --

THE COURT: Well, is Olson going to be testifying live or by a prior depo?

MR. REIDY: He's the potential video witness, Judge.

THE COURT: Okay.

MR. REIDY: So live in essence.

THE COURT: Yeah.

MR. RATHKE: So we feel that -- and we did object to the evidence coming in on the Summer Johnson deposition, and then the Court made its ruling.

THE COURT: But that ruling was predicate I think on a representation by the defense that the doctor was relying on

that.

MR. RATHKE: Exactly, exactly. And so now it's clear that the doctor isn't relying on it. The evidence has come in subject to one limited instruction. We would request that the Court exclude it entirely, instruct the jury that they are to disregard it, indicate in its instructions that the reason they heard it was based on a representation by the defense which turned out not to be the case.

THE COURT: Yeah, I'm not going to do that. I appreciate that, but anyway, let's -- what's the defense position?

MR. REIDY: Judge, I think we can advance the ball in significant part in that we're not going to attempt to lay a foundation and offer the outtake photographs of the home in the later year that was the subject of some debate.

THE COURT: Yes.

MR. REIDY: We've now decided not to do that.

THE COURT: Okay.

MR. REIDY: With respect to the rest of this, I'd actually have to defer to my colleague Mr. Scannapieco if I may.

THE COURT: Sure. Thank you.

MR. SCANNAPIECO: So, Your Honor, when we submitted our response to their initial objection on this issue, Olson relied on a variety of records that were provided including the Able Kids records. And if you review his submission to --

THE COURT: I did, and basically he said he relied on it, but it didn't make any difference to his opinion so . . .

MR. SCANNAPIECO: The point is is that he was saying I looked at these circumstances, they are not either exceptional in one direction or the other. So, for example, he's not saying the circumstances that, you know, only in this case would you have a group care home. But on the opposite end, if there were testimony that -- which they ended up not introducing that the family said we're in an exceptionally unique position to care for Jeanine in the home whereas other people would not be in that position, his opinion is is that by looking at those records there are -- you know, he's seen some problems with the family that have existed over time. They're not exceptional, but they are typical of what happens with these types of families. So he looked at it in that sense, not to say, well, I'm --

THE COURT: Yeah, but what's that got to do with the bedbug evidence? I think we're talking about the bedbug evidence here, so here's my take on it. You tell me if I'm wrong, or maybe one of the other lawyers can chime in too. He reviewed it, but he didn't actually rely on it for his opinion because it made no impact. It had no impact on his opinion. And isn't that correct?

MR. SCANNAPIECO: That's what he testified to.

THE COURT: Yeah. So you may have only told me he

reviewed it. I don't remember exactly what you told me. But you knew he had reviewed it when we were arguing about it earlier when I admitted it.

What's your position now with regard to the bedbug evidence? I take it you're not going to try and -- you're not going to -- you're not going to ask the expert about that.

MR. REIDY: And we're not going to argue it, Judge.

THE COURT: And you're not going to argue it. So the only thing is what, if anything, I should do about the fact that it came in with regard to Summer Johnson; right?

MR. REIDY: And we're sort of open, Judge. Since we're not going to argue it --

THE COURT: You don't --

MR. REIDY: -- if the defense (sic) thinks it underlines it to tell the jury to forget about it, then they don't have to do that. If they would rather tell the jury to forget about it, that's fine with us. We're not going to argue it.

THE COURT: Yeah. Well, I mean, one way to do it would be to ask the doctor when he testifies did that have any impact on his opinion, no. Or you can just have me -- because they're not going to raise it with the doctor, maybe you don't want to raise it again with the doctor, call more attention to it.

So would you like me to just say -- tell them that I

previously gave them an instruction that it was offered for a limited purpose and now there's no purpose for which it was offered so it's been stricken, something like that?

MR. RATHKE: Yes, Your Honor. That would be the bedbugs, the fleas, and the baby not being hygiene -- proper hygiene.

THE COURT: Well, let's -- yeah. Are some of your experts going to testify about all the hygiene issues that you raised with the mother? I assume that, that --

MS. GHEZZI: Well, I mean, Your Honor, his experts talked about it. Janine Jason talked about it. Megan Surber talked about it. The fleas are in. They had the dog in 2008. He's going too far. The bedbugs are one thing. But the other stuff, it's come in through Megan Surber, and it's come in through Janine Jason as well.

THE COURT: So is there anything besides -- do you agree that it would be okay to tell the jury that they should just disregard the bedbug evidence?

MS. GHEZZI: Yes, Your Honor.

THE COURT: Okay. Is there anything else you're asking me to tell them to disregard?

MR. RATHKE: Well, yes. The not -- I mean, bedbug is one way of summarizing it, but it wasn't just bedbugs. It was that the dog had fleas in 2011. That's what he testified to or that's -- that was part of it and that the baby was in a -- not

in a clean state when visited by Summer Johnson. The reason Megan testified about bedbugs is it was already in there, so I needed her to explain it.

THE COURT: Miss Ghezzi?

MS. GHEZZI: Your Honor, if he's talking about fleas in 2011 or 2012, that's fine. But there's evidence in the case about fleas in 2008 when Jeanine came home. That's in the record through the mother and through Janine Jason. That's there. So I don't know that the jury's going to be able to differentiate fleas in 2008 between fleas in 2011 and 2012. Our understanding is they got rid of the dog -- you know, they didn't have a dog in 2010 and 2011 and 2012. They had a dog in 2008 with fleas and flea infestations. That's in the record.

MR. KING: Your Honor, may I speak to the issue just briefly?

THE COURT: Sure.

MR. KING: We have no objection to evidence contemporaneous with this child's illness. Clearly that's relevant. That's fine.

But the evidence later through the physical therapist about the child's condition being unclean, about fleas, about all that stuff, that's prejudicial evidence that has nothing to do with this case. It's in solely on the representation of the defense that their expert needed it when, in fact, he doesn't. It should never have been heard by this jury. We're very

troubled that it prejudices this jury against this case. That's what -- that's why we're talking about it.

The 2010, 2012, the baby's not clean, there's fleas, there's et cetera, et cetera, et cetera, years after the onset of the illness, pure prejudice, no purpose for it. They could have asked their expert and clarified. They didn't. The expert said, "I don't care about that stuff." It never should have been heard by this jury. That's what we're troubled by.

And I'm not sure how to fix it, frankly. The jury clearly has to be told it shouldn't have been in the case, they shouldn't have considered it for any purpose at a minimum.

THE COURT: Yeah, but exactly what I'm going to tell them about what evidence is troubling, and I don't want to do that on the fly. So here's what I suggest. There's -- do you think you could work out a -- agreed language? That would be the best thing to do rather than to have me just extemporaneously -- and I might not correct --

MR. KING: We'll attempt to do that. Yeah, we'll work at that.

THE COURT: Okay. And then if -- you know, there's, I think, a fair chance you won't be able to agree, and I understand that. And that's not a criticism. Then I'll decide exactly what to say, but we'll have some more precise language, and I'll hear from both sides as to what that language should include or what it shouldn't include, and then I'll decide, and

then I'll tell the jury.

But I'm not going to get into the representations and whose fault it is. That's -- that would be prejudicial in my view. So I'm just going to say I made a mis -- some probably -- I made a mistake in admitting -- I don't know if I'll say that. I probably will but that -- or I'll just tell them to disregard it. But why don't you try and come up with language so they'll know what it is they're allegedly disregarding; okay? Anything else?

MR. RATHKE: We did agree on the Exhibit 141 to redact and readd, recalculate. But I won't have that by 10:00, but I assume that that's not a problem.

THE COURT: Just refresh my recollection. What is 141? Is that that Medicare summary?

MR. RATHKE: Yes.

THE COURT: Okay.

MR. RATHKE: Then on 160, I'm still waiting for a response from the defense, but as I understand it, they will agree to a stipulation as to the last sentence.

MR. SCANNAPIECO: Yeah, we're just waiting for them to send us the stip.

MR. RATHKE: I already sent you --

MR. SCANNAPIECO: We're just waiting --

MR. RATHKE: The last sentence.

MR. SCANNAPIECO: Okay.

THE COURT: They're objecting to the last sentence or . . .

MR. SCANNAPIECO: No, no, no.

THE COURT: No.

MR. RATHKE: That's the stip.

MR. SCANNAPIECO: We're coming up with a stipulation for the last sentence. We asked that it get sent over. I was waiting for that, but we can --

MR. RATHKE: It's the quote from the last sentence. You've already got it.

THE COURT: Hey, don't be arguing with each other in front of me.

MR. RATHKE: Okay. Then the last evidentiary issue --

THE COURT: You can go out behind the building and do that but . . .

MR. RATHKE: The last evidentiary --

THE COURT: I get to argue with you, but you don't get to argue with each other.

MR. RATHKE: The last evidentiary issue would be Exhibits 171, 172, 173, and those are the web pages. The objection is relevance, not foundation, not hearsay. The objection is relevance. That's -- they cite various provisions of Rule 4-0 this and 4-0 that, and that's what's cited for their objection in the documents that they submitted for the final pretrial order. That being the objection, it's clear that the

three items are relevant.

THE COURT: Well, how are you going to -- well, are you going to have their witnesses talk about them?

MR. RATHKE: Well, they're just -- they're just evidence that they say is not relevant. We don't have a witness to put them through. They didn't ask for -- they did not object on foundation. Had they objected on foundation, we'd have to re -- we'd have to reach that issue. Their only objection is foundation -- or excuse me, is relevance. The items are clearly relevant, so, therefore, they should be admitted.

MS. GHEZZI: And, Your Honor, our position was that they dated from 2009 to 2011 and they're not relevant to what the mother or the father saw before they used the powdered infant formula and nor did any of the treating physicians. They had absolutely no evidence in the record to connect those websites up to something that predated 2008 or that occurred in 2008. They just pulled it off a website dated 2009 up through 2011, so that was our objection to relevance.

THE COURT: And, you know, I haven't read it all. What's the relevance of it?

MR. RATHKE: Exhibit 171 provides some history of the development of the powdered products. Exhibit 172 --

THE COURT: Yeah, and why does that help your case with the jury just out of curiosity?

MR. RATHKE: Just gives them some background. It's

not critical. Exhibit 172 relates to NeoSure and its history. And Exhibit 173, amongst others, talks about Abbott being a leader in the industry.

THE COURT: Well, there are going to be Abbott people testifying. Can't you get most of this stuff in through them?

MR. RATHKE: The witnesses that they're calling, Sharon Bottock is not going to be conversant. When I asked her any such questions at her deposition, she didn't know.

MS. GHEZZI: Well, Your Honor, in terms of 171, I mean, this is a fact sheet. And, I mean, it basically describes all different products in the Similac brand, none of which are relevant in the case except NeoSure. I mean, we've got Advance Organic, Similac Sensitive, Sensitive Isomil Soy, Sensitive for Spit-Up, Alimentum which is specially designed for food allergies. Then there's NeoSure. Then there's, you know, special care for diarrhea, Go and Grow. I mean, they have the -- they have the package insert and all of the information relating to NeoSure and the NeoSure that's at issue in this case specifically. But these other -- these other --

THE COURT: There's like one paragraph on NeoSure in this --

MS. GHEZZI: Right.

THE COURT: -- 172 document.

MS. GHEZZI: Yes. That's correct, Your Honor.

MR. RATHKE: I might want to say in closing that in

1994 Abbott introduced NeoSure in the closing argument. I need an evidentiary basis for it.

THE COURT: Ask one of their witnesses.

MR. RATHKE: Okay.

THE COURT: Yeah. I agree with the defense. You know, there might be some slight exceptionally marginal relevance to some of the -- to something in the document, but the bulk of the document is totally irrelevant, so I'm going to exclude all three of them. And if you were to be so fortunate as to win, I would expect a thank-you note for my ruling.

Anything else?

MR. RATHKE: Not from the plaintiff, Your Honor.

MR. REIDY: Nothing, Your Honor.

THE COURT: Okay. We have the major issue of the case to take up. Mr. Reidy has already read my mind. Do you want the brownies at the first break or the second break?

MR. KING: First break, please.

THE COURT: First break, awesome. They're good in the morning. Thank you.

MR. REIDY: Thank you, Judge.

THE COURT: We'll see you in five minutes. Thanks.

(Recess at 8:24 a.m.)

THE COURT: Please be seated. A juror came in late, so we'll give them a little bit of time to get -- are they ready?

CSO ABBE: Not yet.

THE COURT: Okay. You just tell me when they're ready, Bill.

(The jury entered the courtroom.)

THE COURT: Good morning. Is that bottled water, gin, or vodka, huh? The lawyers are going to assume it's bottled water.

Okay. Where are we, Miss Van Wyhe? Good morning.

MS. VAN WYHE: Good morning. We are ready to call Brad Puetz, Your Honor.

THE COURT: Okay. Is he here?

MS. VAN WYHE: He is.

THE COURT: There he is. Sir, if you'd just come forward, I'll swear you in. Would you raise your right hand.

BRAD PUETZ, PLAINTIFF'S WITNESS, SWORN

THE COURT: Thank you. Please be seated in the witness box, and you can adjust the chairs and the microphones so you can speak directly into the microphones. And would you tell us your name and spell your last name, please.

THE WITNESS: Brad Puetz, P-u-e-t-z.

THE COURT: Thank you.

Counsel?

MS. VAN WYHE: Thank you, Your Honor.

DIRECT EXAMINATION

BY MS. VAN WYHE:

Q. Mr. Puetz, where do you work?
A. At the Sioux City drinking water plant.
Q. And what is your title there?
A. Operations supervisor.
Q. How long have you worked at the water treatment plant?
A. A little over ten years.
Q. Do you have any special licenses or training associated with your work at the Sioux City water treatment plant?
A. Yes. I currently hold the highest drinking water certificate in the state of Iowa which is a grade 4. And we are also required to carry CEUs each year.
Q. Does the city have to follow any state or federal regulations associated with the municipal drinking water?
A. The regulations that Sioux City follows are both mandated by EPA and the Iowa Department of Natural Resources. There are a lot of regulations that we have to follow for Sioux City drinking water.
Q. Okay. Can you describe what the city does to make sure that its drinking water is safe, kind of the process that you go through.
A. Yeah. We use two main processes, the first being filtration. Sioux City uses dual media filters, sand and anthracite coal. That's the first process the water goes through. The second and most important process is that of disinfection. We use chlorine gas at the Zenith water treatment

plant to ensure that the water is disinfected properly.
Q. Are you familiar with E. sakazakii or cronobacter?
A. Only from the information from this case. I was asked to provide documentation to local counsel on the case and have done just very little research on that bacteria.
Q. If there was E. sakazakii or cronobacter in the municipal water, would the treatment that the city provides kill that bacteria?
A. Absolutely.
MR. SCANNAPIECO: Objection. Foundation.
THE COURT: What's insufficient about the foundation?
MR. SCANNAPIECO: He's being asked to provide an opinion on whether water treatment would kill E. sakazakii, and he just testified that he has little familiarity with the bacteria.
THE COURT: Overruled.
BY MS. VAN WYHE:
Q. Go ahead and answer.
A. Can you ask me the question again, please?
Q. Sure. If there was E. sakazakii cronobacter in the municipal water, would the treatment that the city provides kill that bacteria?
A. My understanding of the bacteria is that it falls in a coliform group. All of the bacteria that is tested for in the city falls in that group. Basically when a bacteria sample is

run, it's -- the coliform group is an indicator test. So the individual bacteria itself would not be tested for, but the disinfection process that we -- that we use at the Zenith water plant would inactivate any bacteria that falls under that group. So yes.

Q. You're aware that the time frame when the minor child in this case got sick was in April 2008; is that right?

A. That's correct.

Q. Did you look at the city water records for April 2008?

A. Yes.

Q. And was there cronobacter or E. sakazakii bacteria in the city water in April 2008?

A. I don't know that answer. What I can say is the water that the city treated was free of any bacteria in April of 2008.

Q. Okay. So the city water was free of any bacteria, and that would include the cronobacter E. sakazakii if it was in there?

A. That is correct.

Q. Okay. Because that was part of the coliform group that this bacteria's part of; is that right?

A. Correct.

Q. And you checked the water records for every day in April 2008 in preparation for your testimony; is that right?

A. Yes.

Q. Now, you said you've been with the city water department for ten and a half years?

A. Correct.
Q. During that time, has there ever been a notice sent out to city residents that they needed to boil their water?
A. No.
Q. Are you aware of any reported case while you have been with the city water department where someone got sick from the city water?
A. There have been no instances to my knowledge.
MS. VAN WYHE: I have no further questions.
THE COURT: Thank you. You may cross-examine.

CROSS-EXAMINATION

BY MR. SCANNAPIECO:
Q. Morning, Mr. Puetz. My name's Gabe Scannapieco. We've spoken before.
Now, you just testified about treatment at the water plant. You're talking about the treatment at the time the water's in the plant; correct?
A. That's correct.
Q. And so when you speak about the safety of the water in Sioux City, you're not talking about the safety of the groundwater supply before it's treated, are you?
A. Correct.
Q. And also when you're talking about the level of treatment that occurs, that's in the plant. That doesn't necessarily guarantee the quality of the water when it comes out of a faucet

somewhere else in Sioux City; correct?
A. That is correct. The --
Q. Thank you.
A. Okay.
Q. Now, I want to ask you a few questions about some testing that was performed in April 2008 on the groundwater that was being collected by the city's wells; okay?
A. Okay.
Q. Now, your department conducted weekly testing of the water that was collected in -- I believe they're large wells that are by the riverfront that collect water for the Sioux City water supply, correct, in -- let me rephrase that; okay? That was a terribly misworded question.

Your department performed bacterial testing on the city wells used to collect groundwater before that water was sent to the treatment plant; correct?
A. That's incorrect.
Q. Okay.
A. Yeah. Normally we do not take bacteria samples from the raw water.
Q. Okay. But you did do that in April 2008; isn't that right?
A. Can you -- could you provide the documentation for me, please?
Q. Sure, if that would help you remember what you've provided.
A. Okay. Yes, the document that you have placed in front of

me is a bacteria sample from one of our wells which is the riverfront collector well which at the time would have been done once weekly.

Q. Okay. And that's the one at Chris Larson Park?

A. That's correct.

Q. And this test shows the quality of the groundwater that's going into the city wells; correct?

A. That's correct.

Q. And I believe that the person that went out and collected that test, that was you?

A. That'd be me.

Q. And is it correct that all the testing of that weekly testing during the month of April 2008, all of it was positive for coliforms in the groundwater?

A. That looks to be correct, yes.

Q. Okay. Thank you. Now, let's talk a little bit about the disinfection that the city does with the water supply. The city you said uses filtration before it uses chlorination, and the filtration, that is just -- it uses sand, and the water travels through the sand?

A. Yes, and the anthracite coal, yes.

Q. Okay. And then you have to use chlorine to address any microbes that might be in the water?

A. Correct.

Q. Now, in order to achieve disinfection, you have to have a

minimum level of chlorine in the water; is that correct?
A. The calculation used to determine whether or not we disinfect the water properly is called a CT calculation, basically contact time, and it's a calculation based on the chlorine residual and the temperature of the water at the time. And during April of 2008, all of our CT calculations met requirements.
Q. Okay. And so that was the CT requirements that you measured at the plant.
A. Correct, after disinfection.
Q. And the residual chlorine, are you talking about something called free chlorine?
A. Free chlorine, that's correct.
Q. And free chlorine is the amount of chlorine that's left in water that can interact with microbes?
A. That's correct.
Q. And you don't have enough free chlorine in water, it's -- you wouldn't be able to disinfect any microbes that would come into contact with the water; correct?
A. There's a minimum amount of chlorine as you said. The disinfection process probably does happen, but we can't assure that that is the case.
Q. Sure. But there is a minimum amount that is required to assure that microbes are killed.
A. That's -- that's correct.

Q. Okay. And you talked about being regulated by the EPA and the Iowa DNR and there being numerous regulations. Am I correct that the Iowa DNR requires a level of .3 milligrams per liter of chlorine to assure disinfection?
A. That is correct.
Q. And if water drops below that level, it's not considered potable water anymore; correct?
A. It's considered inadequately disinfected.
Q. Now, chlorine levels drop in Sioux City's water supply from the time that it's in the water plant to the time that it reaches people's homes; correct?
A. That's correct.
Q. And so Sioux City not only tests some of the water that's from its plant, but it actually goes out, and it looks at houses and different faucets across the city to see the levels of chlorine that are in that water; correct?
A. That's correct.
Q. And that's the only way that you can know if the water that's going into a specific area of town has the required level of chlorine to assure disinfection of anything it encounters during the distribution.
A. That's correct.
Q. And you performed these tests through something called -- I believe there are some handwritten forms that you have at the plant that show a test at the plant on a day and then show a

test taken somewhere out in the city; correct?
A. That's correct.
Q. And then there are also routine testing where about ten samples are taken from a rotating schedule of locations?
A. That -- at that point in time in 2008, we were required to take 90 bacteria samples per month.
Q. Okay. And when that was done, it was done at -- you know, in groups of about 10 to 12 at a time.
A. That's correct.
Q. And then lastly, the city takes tests that are called special tests which is if you're interested in knowing the water quality in a specific address, you have to go to that address and test the water, or else you're not a hundred percent sure whether the water has bacteria or sufficient levels of chlorine; correct?
A. That's correct.
Q. Now, you talked about collecting and reviewing some documents for this case. Do you recall that those documents included a handwritten plant form for the month of April 2008?
A. Was that a chlorine residual imp --
Q. Let me bring it to you.
A. Okay.
MS. VAN WYHE: Your Honor, I object to this exhibit on relevance.
THE COURT: Well, he's not offering it.

MR. SCANNAPIECO: Yeah.

THE COURT: So the objection's premature. We'll see if he offers it. I think he's using it to refresh the recollection of the witness.

BY MR. SCANNAPIECO:

Q. Mr. Puetz, have you had the opportunity to look at that?

A. I did -- I did look over this information when it was requested by local counsel. I'm fairly familiar with the information.

Q. Okay. So does this document refresh your memory as to when we talked about there was a form that showed a test taken at the plant and then a test taken somewhere out in Sioux City? Does that refresh your recollection about those tests?

A. Yeah.

Q. And the results of those tests?

A. Yeah.

Q. Now, the way that I understand it is that -- these forms are filled out is that there's an entry for each day. So if we look at the top, that's April 1. And if we move ourselves, you know, down, April 2, April 3, April 4, April 5, and so on?

A. That's correct.

Q. Okay. Do you recall what the results were for system testing on April 17, 2008?

A. I see that information, yes.

Q. Okay. And am I correct that the results for system testing

taken out in Sioux City on April 17, 2008, were a level of .16 residual chlorine; is that correct?
A. That's correct.
Q. And the level mandated by IDNR for potable water is .30 milligrams per liter; correct?
A. That's correct.
Q. So this is barely 50 percent of that required minimum; correct?
A. That's correct.
Q. And that test was taken at 2404 Riverside Boulevard; is that right?
A. That's correct.
Q. And do you know where that is?
A. I don't know where the exact -- I mean, I know the area, but I don't know the exact location.
Q. Okay. Am I right to assume that it's near the neighborhood of Riverside?
A. Yes.
Q. And does this form also show if you look between the test that was taken at the plant and the test that was taken at that Riverside location that the amount of residual chlorine in the water had dropped over 90 percent?
A. That is correct, but you cannot assume because there is water already in the distribution system, water that has aged, so we cannot use the plant disinfection level for that day to

determine a number of decrease for the plant or for the system sample.

Q. Okay. So if I understand correctly what you just said, you're saying that if we look at the levels that we have at the plant, that's not going to tell us anything about the levels that we would see in the city because there's older water sitting in the system and there's other things that may affect the quality of the water there. When we're looking at plant results that you say are in the CT inactivation ratio, that's only telling us what's going on at the plant. Is that --

A. That's correct.

Q. Did I understand you correctly? I'm going to hand you some more of your testing records because I have sort of a general question that you may want to refer to some too. Mr. Puetz -- I mean Puetz -- I'm sorry -- after looking at the records, am I correct in my assumption that the closest water sample taken in the second half of the month of April 2008 to the Riverside neighborhood was the test that we just talked about, that test from 2404 Riverside Boulevard? And if you need to refresh your recollection as to the other tests, please let me know.

A. Give me one second, please. That seems to be accurate.

Q. Thanks. I just have one question about May two thou -- or I'm sorry. I don't want to lose my gold star, but I have a couple questions about May 2008; okay? We talked before about routine testing, and that's where you go out and you check some

of the taps in the city to see what the levels of chlorine are. Am I correct in my assumption that there was a test performed on May 1, 2008, that showed that at that time, unlike April 2008, the chlorine levels near the Riverside neighborhood were, again, normal?

A. Yes, they were normal.

MR. SCANNAPIECO: No further questions.

THE COURT: Any redirect?

MS. VAN WYHE: No, Your Honor.

THE COURT: Any questions from the jury? Doesn't look like it.

Thank you. You may step down.

What's next?

MS. VAN WYHE: Your Honor, we would call Louise Deitloff.

THE COURT: Okay. Good morning. You've been so patient this whole time.

LOUISE DEITLOFF, PLAINTIFF'S WITNESS, SWORN

THE COURT: Thank you. Please be seated. Adjust the chair and the microphones. And when you're ready, tell us your name, please, and spell your last name.

THE WITNESS: Okay. My name is Louise Deitloff, D as in David e-i-t-l-o-f-f.

THE COURT: Thank you.

DIRECT EXAMINATION

BY MS. VAN WYHE:
Q. Where do you work?
A. I work at Security National Bank.
Q. And what is your title there?
A. Wealth management advisor.
Q. Is it your understanding that Security National Bank was appointed by the Woodbury County District Court to be the -- Jeanine's conservator?
A. Yes, that's correct.
Q. And on January 7, 2011, did the Woodbury County District Court issue an order giving permission to bring this lawsuit?
A. Yes.
Q. What is your understanding as to why Security National Bank is the conservator for Jeanine and the plaintiff in this lawsuit?
A. Well, Security was asked to serve as the -- as a corporate conservator for Jeanine since she's a minor child, and we bring a lot of experience and continuity and things that work well with looking after any financial matters that may be -- that this child may need in the future.
Q. To your knowledge, does Jeanine have any assets other than this claim against Abbott?
A. No.
Q. If the jury finds for the plaintiff and awards money to Security National Bank in this case, what will happen to the

funds?
A. The funds will be held at the bank, and we will manage those. Like I talked about, we have experience managing assets for all kinds of clients and conservatorships and trusts and things. We will manage those, fulfill our fiduciary duties. We'll work closely with the court. We would -- we have procedures so we would set up what the standard, what her needs are, and the costs that are associated with those, and we would provide those when they're needed.
Q. How much oversight does the bank have on that account? In other words, can you explain the process that Jeanine's caretakers or parents would have to go through to get funds out of that account?
A. Yes. Well, like I talked about, we'd set up and get approved what the standard course of her needs would be, and we'd have the expenses of those, and we would get those preapproved. We have a process where we do s -- we understand what the requests are, we do some independent research and, you know, make sure that those are in Jeanine's best interests and that she does need those. Then we would get that approved through an internal committee.
I would do the research, and then I would present that to them. They would maybe come back and ask me more questions that I may have to do further research on.
Then once it's approved by our committee, it would

also need to be approved by the court. So any monies that are expended for her care would have the oversight of the court in addition to our internal oversight.

MS. VAN WYHE: Thank you. I have no further questions, Your Honor.

THE COURT: Thank you.

CROSS-EXAMINATION

BY MR. REIDY:

Q. Is it Miss Deitloff?

A. Deitloff actually.

Q. Deitloff, I'm sorry.

A. That's okay.

Q. I'm Dan Reidy, Miss Deitloff. We've not met before; is that right?

A. No.

Q. The conservatorship that the bank has, you mentioned that that's while Jeanine is a minor?

A. Well, in this case since Jeanine will never be capable of managing her own affairs, this would go on for her lifetime.

Q. And at the end of her life, what happens to the conservatorship?

A. Well, that's a good question. I would suppose the conservatorship would end, but it's my understanding that if funds are provided for Jeanine's care, then in addition to the conservatorship, there would be a trust established. The bank

would serve kind of a dual role as the trustee and the conservator. When this trust is created, there would be provisions within the trust that the bank would have to follow. And I would imagine as with the other trusts that I manage that there would be a provision inside the trust for what would happen with those funds at Jeanine's death. You know, one thing may be there could be a foundation or something established.

Q. I don't want you to speculate.

A. Okay.

Q. Jeanine can't tell you what to do with the money, can she?

A. No, she's not capable of that.

Q. And so if the conservatorship ends, is one possibility that the money would pass according to the Iowa laws of what happens to money when somebody passes without a will?

A. I don't know the answer to that question.

Q. So do you know whether or not the money would pass to the parents if they were still living as Jeanine Kunkel's heirs?

A. I'm not familiar with that law. So, you know, I would just follow what the court would tell us to do.

MR. REIDY: Thank you.

THE COURT: Any redirect?

MS. VAN WYHE: No, Your Honor.

THE COURT: Okay. Any questions from the jury? Doesn't look like it.

Okay. You may step down.

MR. RATHKE: Your Honor, at this point we'd like to read the deposition of Pamela Anderson.

THE COURT: Okay.

MR. RATHKE: This is a deposition which occurred on September 10 -- or excuse me, September 30, 2011. I was asking the questions. Ms. Anderson was answering them. And Attorney June Ghezzi represented Abbott.

(Deposition designations of Pamela Anderson were read in open court.)

THE COURT: What's next? Why doesn't everybody take a stretch break.

Okay. Thank you. Please be seated. Another deposition?

MR. RATHKE: Yes, Your Honor. This is the deposition of Larry Williams which was taken on October 5, 2012, and Pat Persons from our office will be playing the part of Dr. Williams. And if there's any objections by counsel, that would be read -- by Abbott counsel, that would be read by Ms. Van Wyhe.

THE COURT: Could you move that microphone a little closer to you? Thank you.

MR. RATHKE: Okay. You all set? All right.

(Deposition designations of Larry Williams were read in open court.)

THE COURT: What's next?

MR. RATHKE: Your Honor, with the Court's permission, we're ready to run the two videos that have been discussed in the testimony, first the day in the life and, second, the therapy video, and those should take about a total of 30 minutes.

THE COURT: Okay. Why don't we give everybody a stretch break, and then we'll see the two videos, and then we'll take our morning recess.

THE COURT: Thank you. Please be seated.

(Exhibit 142 was played in open court.)

MR. RATHKE: Your Honor, that ends that video. We have one more video to play which is about 15 minutes.

THE COURT: Okay. Thank you. Why doesn't everybody take a stretch break while they queue up the last video.

MR. PERSONS: All set, Your Honor.

THE COURT: Okay. Thank you. Please be seated.

(Exhibit 143 was played in open court.)

THE COURT: Mr. Rathke, does the plaintiff have any additional evidence?

MR. RATHKE: The Medicaid issue we've talked about, so we'd be offering that, and we discussed that earlier so . . .

THE COURT: Are you going to offer that at this time or at some later time?

MR. RATHKE: I can offer it now.

THE COURT: Okay.

MR. REIDY: There's no objection, Judge.
THE COURT: Okay. Thank you.
MR. REIDY: If that's the question.
MR. RATHKE: Your Honor, ladies and gentlemen of the jury, the plaintiff rests.
THE COURT: Well, I thought you were going to offer the document.
MR. RATHKE: We have to --
THE COURT: I'm not understanding what you're doing.
MR. RATHKE: I'm sorry. We have to change the document.
THE COURT: Oh. Well, then I asked you if you were going to -- okay.
MR. RATHKE: I haven't got the document ready right now.
THE COURT: Well, that's what I asked you. Okay. So you rest, but you've got an agreement on the document, and that document will be coming in.
MR. RATHKE: Yes, Your Honor.
THE COURT: Okay. And, Mr. Reidy, is that correct?
MR. REIDY: Yes, Your Honor, that's correct.
THE COURT: Okay. Thank you.
MR. KING: May I confer with counsel for one minute, Your Honor?
THE COURT: Yes.

MR. KING: Your Honor, just one further evidentiary item that counsel and I, I think, will resolve, it would be an offer of evidence going to the financial condition of Abbott as it might bear on punitive damages.

THE COURT: Okay.

MR. KING: We've agreed to work --

THE COURT: And you're going to have a stipulation about that?

MR. KING: Yes, we've agreed to work that out for later admission.

THE COURT: Okay. Okay. For later admission. And the defense doesn't object that it will come in later. Okay. Thank you.

So the plaintiff has rested subject to -- there are two additional pieces of evidence that the parties are just kind of working out the numbers on actually. They both involve numbers, and you'll be getting that information. But the plaintiff has rested. And we'll take a recess, let's see, until -- we'll be in recess until 10 . . .

MS. GHEZZI: Your Honor, if I may?

THE COURT: Yes.

MS. GHEZZI: We have Dr. Shulman who we thought was going to get on between 9:30 and 10. He has to be finished today if that has any consideration in your . . .

THE COURT: So he has to be finished today?

MS. GHEZZI: Yes, yes, Your Honor.

THE COURT: You're not going to be able -- we're not going to be able to finish him the whole rest of the day?

MS. GHEZZI: No, no. We -- yes. I'm just telling you we thought he was going to be on between 9:30 and 10.

THE COURT: Well, I know you thought that, but that didn't happen, so are you telling me if I give the jury a 25-minute recess --

MS. GHEZZI: No, no, no.

THE COURT: -- they're not going --

MS. GHEZZI: No, no, Your Honor.

THE COURT: -- you're not going to get --

MS. GHEZZI: No.

THE COURT: Well, then why did you even -- what's the purpose of what you're doing?

MS. GHEZZI: Just because the schedule is a little bit off, and I just wanted to share that with Your Honor. That's all.

THE COURT: Okay. Thanks for sharing.

Members of the jury, we'll be in recess until 10 minutes to 11. Thank you.

(The jury exited the courtroom.)

(Recess at 10:22 a.m.)

THE COURT: Ready to have the jury brought in?

MS. GHEZZI: Yes, Your Honor.

THE COURT: Thank you.

MR. REIDY: Thank you for the brownies, Your Honor. They were great.

MS. GHEZZI: Delicious.

THE COURT: Oh. I imagine federal judges in Colorado probably won't be serving brownies to the lawyers.

MS. GHEZZI: That is correct. That would be correct.

MR. RATHKE: Okay. That went over my head.

THE COURT: Maybe if you're a state court judge you would but not a federal judge; right?

(The jury entered the courtroom.)

THE COURT: Thank you. Please be seated.

And, Miss Ghezzi, you can call your first witness.

MS. GHEZZI: Your Honor, the defense calls Dr. Stanford Shulman.

THE COURT: Thank you. Doctor, if you'd come forward, I'll swear you in, just anywhere in the middle here. Would you raise your right hand, please.

STANFORD SHULMAN, DEFENDANT'S WITNESS, SWORN

THE COURT: Thank you. Please be seated. And you can adjust the chair and the microphones so you can speak directly into them. And would you tell us your name, please, and spell your last name.

THE WITNESS: My name is Stanford T. Shulman. That's S-h-u-l-m-a-n.

THE COURT: Thank you.

Miss Ghezzi?

MS. GHEZZI: Thank you, Your Honor.

DIRECT EXAMINATION

BY MS. GHEZZI:

Q. Dr. Shulman, where are you currently employed?

A. I'm currently employed at the Lurie Children's Hospital in Chicago and Northwestern University Feinberg School of Medicine in Chicago.

Q. And can you tell the jury your job responsibilities at the Lurie Children's Hospital of Chicago.

A. Yes. I'm the head of the division of infectious diseases at the Lurie Children's Hospital, and I'm the director of the hospital infection prevention and control program.

Q. And do you have a role as the hospital epidemiologist?

A. Yes, I am the hospital epidemiologist with respect to the infection control program, yes.

Q. Do you have any other titles at the hospital?

A. I'm the medical director of the microbiology laboratory, and I'm the past director of the fellowship program in pediatric infectious diseases which I gave up after 33 years.

Q. And how long have you been chief of the division of infectious disease and the hospital epidemiologist at what used to be Chicago -- or Children's Memorial Hospital and is now the Lurie Children's Hospital of Chicago?

A. Thirty-five years.
Q. Do you have any current teaching positions?
A. I'm a professor of pediatric infectious diseases at the Northwestern University Feinberg School of Medicine, and I'm responsible for the education of our pediatric infectious disease fellows, the pediatric residents -- we have about 90 pediatric residents currently -- and the Northwestern medical students with respect to infectious diseases.
Q. Thank you. Could you tell the jury your educational background, please?
A. Yes, I graduated from University of Cincinnati, and I then -- with my bachelor's degree, and then I graduated from the University of Chicago Medical School with my M.D. degree. I then became a resident and chief resident at the University of Chicago and -- in pediatrics. I then did some training at the Institute For Child Health in London, England, for a relatively brief period of time and did training in pediatric infectious diseases and immunology at the University of Florida.
Q. And are you board certified in any specialty?
A. Yes, I'm board certified in pediatrics and pediatric infectious diseases.
Q. And what does it mean -- can you tell the jury what it means to be board certified?
A. It means that one has completed training, nowadays three years of training, in pediatric infectious diseases as well as

three years of training in pediatrics to become board certified in those two specialties.
Q. And does it involve special testing of any kind?
A. Yes. In addition to completing a course of education, one has to be certified by passing a test and then becoming recertified on a periodic basis, every seven to ten years.
Q. And have you kept up your board certifications?
A. Yes, I have.
Q. Can you tell the jury, please, if you have any memberships in pediatric infectious disease professional or scholarly associations.
A. Yes. I'm a member of the Infectious Disease Society of America. I'm a member and past president of the Pediatric Infectious Disease Society which is the largest such society in the world. I'm -- yes.
Q. Have you authored any books on pediatric infectious disease and book chapters?
A. Yes. I've authored 6 books and about 75 book chapters.
Q. And have you -- do you have any publications on infant bacterial meningitis?
A. Yes, I have a few publications on that topic and mostly chapters.
Q. And do any of them deal with in any way E. sakazakii?
A. None of them deal solely with that, but in chapters on bacterial meningitis in children, I believe there's some mention

of E. sakazakii to be complete.
Q. And as an expert in the field of pediatric infectious disease and infectious disease epidemiology, what were you asked to do in this case?
A. I was asked to review medical records, government records, depositions, and other documents and to assess whether there's reasonable degree with -- reasonable degree of medical and scientific certainty whether Abbott's NeoSure powdered infant formula was the source of the bacterium that caused meningitis in the Kunkel child.
Q. And did you reach an opinion as to whether or not Abbott's NeoSure powdered infant formula was the cause of the infant's meningitis infection to a reasonable degree of medical and scientific certainty?
A. Yes, I did.
Q. And what was that opinion?
A. That opinion is that Abbott's NeoSure powdered infant formula did not cause the baby's bacterial meningitis.
Q. And we're going to go into this in some detail, but can you summarize, please, for the jury the bases for your opinion.
A. Well, the bases are, number one, there's no microbiologic evidence after extensive testing of the powdered infant formula that it was contaminated with the particular organism; number two, that the timing of the baby's infection I believe began -- the earliest symptoms began essentially simultaneous with the

first powdered infant formula feeding; and thirdly, that because enterobacter sakazakii is such a widespread, ubiquitous organism in our environment that there had been inadequate or insufficient testing of environment sources to rule them out as the cause of this infection.

Q. And did you have a chance to review the microbiological testing that you mentioned just a moment ago, the results of the microbiological testing?

A. Yes, I did.

Q. Did you review the results of the testing by the Centers For Disease Control?

A. Yes, I did.

Q. If you look on -- can you see that? Can you see that, Dr. Shulman?

A. Yes.

Q. Okay. This is Exhibit 2153, and can you tell on the first line here what was the specimen that was undergoing testing by the CDC in that line?

A. Yes, it was the infant formula, the Similac NeoSure, with that particular number and date.

Q. You have to talk into the microphone.

A. I'm sorry. It was the infant formula designated Similac NeoSure with particular registration number and the date, and the can was opened.

Q. And the can was opened you said?

A. Yes.
Q. Okay. And what was the test request by the CDC?
A. The test was isolation of enterobacter sakazakii.
Q. And what was the result of that test by the CDC?
A. The result is negative.
Q. Thank you. And did you review the testing that the FDA did?
A. Yes, I did.
Q. And do you recall how many -- how many other cans of Abbott's NeoSure powdered infant formula from batch 61281RE were tested?
A. Yes, I think 17 additional batches were tested.
Q. Doctor, I'm putting up on your screen Exhibit 1009B. Do you see that?
A. Yes.
Q. Can you see the lab conclusions at the end of that test?
A. Yes. Yes. It says no enterobacter sakazakii was recovered from 17 individual subs examined, and no sakazakii MMS operon was detected in 17 subs using reverse transcriptase PCR.
Q. Okay. And those are the tests that were done by the FDA; correct?
A. Correct.
Q. Do you have any reason, doctor, to doubt the results of the CDC's testing on that can of NeoSure?
A. No, none at all.

Q. Do you have any reason to doubt the FDA's testing on the 17 additional cans of NeoSure?
A. Not at all, no.
Q. Did you review any other testing data from Abbott's finished product testing?
A. Yes, I did.
Q. Doctor, I'm putting up on the board -- I mean, I'm sorry, on your screen -- I'm sorry. Excuse me. Pardon me one moment. This is Exhibit 2052. And, doctor, can you see on that exhibit a test result for enterobacter?
A. Yes. Here listed as number 7?
Q. Yes. And what's the result of that test?
A. It's all negative, negative specimen, negative in 750 grams.
Q. Okay. And do you see on the top that I'm going to circle up there that the batch is 61 -- woops. I'm sorry. Sorry. I'm going to take that off, try and get the right one.
MS. GHEZZI: Sorry, Your Honor. Okay. Thank you. I'm sorry. Now we're working.
Q. Do you see 2052, page 0006? Do you see these 2 numbers up here, doctor, 61281RE00?
A. Yes.
Q. Okay. And do you see on that -- for 6128100, that number 7, what the result of that was?
A. Yes.

Q. And what was it?
A. It's all negative in 750 grams.
Q. And then go to the next sample at 61281RE10.
A. Yes. And that's the same result. For E. sakazakii it's negative in 750 grams.
Q. Okay. Thank you. Now, doctor, is there any possibility in your mind that all of that testing somehow just missed E. sak?
A. No, I think that's really not at all possible.
Q. And why do you say that? What's the basis for that statement?
A. Well, we have really -- we have the testing from CDC. We have the extensive testing from the FDA on multiple batches -- 17 batch -- 17 cans that were produced virtually simultaneously or within seconds of the can that the child had been fed from, and we have the additional large volume of powdered infant formula that was cultured by Abbott. All of these being completely negative for E. sakazakii to me makes it virtually impossible that there was any contamination of this product at that time.
Q. Is that at the factory? Are you saying at the factory?
A. Yes, intrinsic -- I'm sorry, intrinsic contamination would be impossible to be present.
Q. If there had been intrinsic contamination occurring at the factory, what would you expect to see out in the real world?
A. Well, out in the world we would expect to see more than a

single case of the infection, because when a food product is contaminated, we generally see -- we always see really multiple cases. We all are familiar with salmonella outbreaks or E. coli outbreaks which are recognized because there's a number of individuals that are infected close in time. And that did not occur in this circumstance.

Q. Okay. And I want to show you Exhibit 2050 which is an Abbott document after the report of the illness in Jeanine Kunkel. And do you see -- can you see the description on May 1, 2008, of what that indicated?

A. Yes. It indicated there was no other E. sakazakii cases registered against this product.

Q. And then on May 19 there was an additional?

A. Additional, again, showed no other E. sakazakii or trends or any sign or symptom registered against this batch.

Q. And if you go down again to May 1, 2008, can you see what the dates are that Abbott was looking at in terms of trying to find out if there were any other E. sak cases registered against --

A. Yes.

Q. -- this product, this entire product?

A. Yes. It runs from the 1st of May, 2006, for 2 years to the 1st of May, 2008.

Q. Okay. And in your experience as a pediatric infectious disease expert, what does this testing data mean in terms of

ruling in or ruling out Abbott's NeoSure powdered infant formula as a cause of the infant's infection?
A. I believe that this really rules out the powdered infant formula as a cause of the child's infection.
Q. If you were treating Jeanine Kunkel as a patient in your hospital knowing what you know from the records that you've seen and her medical records, how confident would you be in telling her parents that the product was not the source of her infection?
A. I would be very confident in telling them that this particular product was not the source of the child's infection, definitely.
Q. Okay. Now, switching gears a little bit, I want to talk a little bit about bacterial meningitis in general.
A. Yes.
Q. And there's been some discussion of it in the case so far, but it was maybe about a week ago. Can you define bacterial meningitis for the jury, please.
A. Sure. Bacterial meningitis is a infection by a germ or bacterium which involves the meninges which is the lining over the brain, over the spinal cord, and it's a serious infection.
Q. And what are the most common types of neonatal and infantile bacterial meningitis in the United States?
A. The most common are what we call Group B streptococcus, and the second most common would be E. coli.

Q. And how many of those are reported annually in the United States currently?
A. Approximately 1,500 to 2,000 cases total.
Q. And in your practice over 43 years treating babies and newborns, have you treated them for bacterial meningitis?
A. Yes, many times.
Q. And about how many times if you can --
A. Probably about 500 cases of bacterial meningitis.
Q. And were any of those cases E. sakazakii meningitis?
A. No, they were not.
Q. And how many cases of infant E. sakazakii meningitis are there per year in the United States based on your experience and research?
A. There are approximately four to six cases each year in the United States of E. sakazakii meningitis.
Q. And what does that mean in terms of the incidence of E. sakazakii meningitis in infants in the United States population as a whole?
A. Well, there's between four and four and a half million newborn babies every year, so four to six cases out of that four million would be about one out of a million.
Q. Do the symptoms of bacterial meningitis in infants differ depending on what kind of bacteria is at work?
A. No, they don't.
Q. Can you tell the jury what are the early symptoms of

bacterial meningitis in an infant?
A. The early symptoms in an infant with bacterial meningitis, irritability, crying, and decreased feeding.
Q. And do these symptoms occur all at once, or do they progress over time or something else?
A. No, they generally show up one at a time and then sort of progress, in the early stages can be a little bit of waxing and waning in terms of symptoms. But overall there's a general progression of severity in terms of the crying, decreased feeding.
Q. And can an infant with meningitis sleep in between bouts of severe crying and irritability?
A. Yes. Babies -- babies who are crying and are extremely irritable do get tired out and exhausted and can fall asleep for a period of time and then awake and resume being inconsolable and crying a lot.
Q. Now, are infants the only humans who get infected by or colonized with E. sakazakii bacteria?
A. No. There's many examples of infections with this particular germ in noninfants, in older children, adolescents, or adults.
Q. Okay. And are you familiar with the World Health Organization report from 2008 that looked at a study from the UK, England, and Wales?
A. Yes.

Q. Are you familiar with that? And do you remember what the results of that study were?
A. The results were that the large majority of isolates of this particular germ in those countries was identified in nonneonates. In fact, out of some 500-plus isolates, I believe there were literally a dozen or two from infants, the rest being from older individuals.
Q. Okay. And have you seen -- have you seen documents from Anna Bowen of the CDC where she is discussing the likelihood of sources and vehicles of infection in infants other than powdered infant formula?
A. Yes.
Q. And, doctor, I'm putting up on the screen Exhibit 1020 which is an e-mail from Anna Bowen from the CDC as you see at the top.
A. Yes.
Q. Okay. To someone at Harvard. Oh, to Janine Jason -- I'm sorry -- yeah, at her Harvard e-d-u. And is this the document that you're referring to?
A. Yes.
Q. And what does that show?
A. It shows that -- down here near the bottom it says --
Q. You have to talk into the microphones.
A. I'm actually working with some data now that suggests many other vehicles for human cronobacter infections exist. I have

had trouble convincing anyone that we have irrefutable evidence of intrinsic contamination, and I am actually working with some data now that suggests many other vehicles for human cronobacter infections exist. I know that FDA has also been working on this hypothesis. Given -- okay. The rest of this is irrelevant.

Q. Thank you. Doctor, I'm going to show you document Exhibit 1011. This is actually -- well, why don't you tell the jury what this is.

A. This is an e-mail to the nurse epidemiologist, Mary Rexroat, at the Iowa Department of Public Health reporting that -- woops.

Q. Sorry. Trying to make it readable for the jury.

A. At this particular hospital we had only one case of E. sakazakii within the last year, but it was on a 62-year-old rehabilitation patient from a cath urine specimen. I'm assuming you don't need this case.

Q. And there's no indication there that on that 62-year-old patient that powdered infant formula had anything to do with his sample or her sample?

A. That would be highly, highly unlikely to be the case.

Q. Where has E. sakazakii been isolated in a hospital setting? Can you tell the jury?

A. Well, it's been -- it's been isolated from patients in hospital settings from a variety of locations such as sputum, urine, bile drainage, many other anatomic locations. But also

because this is such a ubiquitous organism -- it's really found in many, many areas -- it's been identified in air vents, in -- on flat surfaces, ceilings, floors, window sills, dust particles, some equipment within the hospital. So it's extremely widespread throughout the environment even in a hospital.

Q. And have you -- have you seen the literature over the years discussing where it has been found in homes?

A. Yes. There's several articles related to investigations in homes. Particularly this organism is found in the kitchen area and in the bathroom area, particularly around sinks, drains, faucets, countertops, dishrags, sponges as well as flat -- other flat surfaces such as the floor.

Q. Okay. And, doctor, I'm putting up a demonstrative. Are those -- what -- can you tell -- tell the jury what are these sources at the bottom, and what does this -- what does this demonstrative depict?

A. Well, this is a list of various substances where E. sakazakii has been recovered from. It's a summary from these articles down here listed at the bottom. In putting all that information together, you can see there's a huge variety of foods, every food group and then some beverages, lots of environmental areas, dust, water, seeds, and plant stuff in particular, lots of household locations as you can see here, hospital locations as we just mentioned, both equipment as well

as patient and environment, as well as being recovered from a large variety of animals, insects, as well as human beings. And these are various anatomic locations such as appendicitis, CSF which would be meningitis, the eyes, digestive tract, et cetera, et cetera, feces, wounds, et cetera.

Q. Okay. Thank you, Your Honor -- I mean thank you, Dr. Shulman. And which of these potential sources of E. sak should be considered when investigating the source of an E. sak infection such as this case?

A. I think as many as possible that could be investigated and cultured should be done in order to fully assess the situation.

Q. And, doctor, in your work for this case, did you have occasion to review the FDA's most recent position on E. sakazakii in response to a letter from Dr. Janine Jason in 2012?

A. Yes.

MS. GHEZZI: One moment, Your Honor.

Q. This is Exhibit 1021. And, doctor, I'm going to call your attention to this portion of the Benson Silverman letter to Dr. Jason. And have you seen that -- have you seen that before?

A. Yes, I have.

Q. Okay. And what's the import of that?

A. Well, the import is that --

MR. RATHKE: Your Honor, I'm going to object on this doctor -- well, I'm going to object as the evidence is

irrelevant as to what he thinks.

THE COURT: Overruled.

Q. Go ahead.

A. Well, the letter clearly says that the FDA has tested and continues to test large amounts of powdered infant formula from unopened cans of lots implicated in C. sakazakii cases whenever available. In some cases unopened cans have not been available. We're aware that -- also that infant formula manufacturers the last seven years have used stratified sampling plans to test for C. sakazakii in infant formula finished product. The results of case investigations have not indicated that any particular company or product is implicated in C. sakazakii cases. It is unknown how the infant formula becomes contaminated with C. sakazakii, but the evidence from investigations thus far is consistent with packaged powdered infant formula being negative for C. sakazakii when it leaves the manufacturing plant.

Q. And what is the significance of this FDA letter to you as the hospital's epidemiologist for a major children's hospital?

A. Well, it's very reassuring to me in that role to know that the FDA is not expressing their concerns that there are -- there is significant or any contamination of powdered infant formula that they are able to detect currently.

Q. And is powdered infant formula used in your hospital?

A. Yes, there are some powdered infant formulas used in my hospital.

Q. And are any of them used with low-birth-weight babies?
A. Yes, they are.
Q. And what kind are those?
A. Well, in our hospital we have -- we have powdered infant formulas that are used for babies with special metabolic or genetic conditions who need special formulas, and they would be given this -- they are given powdered infant formula.
Q. And in your hospital do you use powdered formula with very low-birth-weight babies?
A. On occasion we do for the same reason.
Q. And are these babies who are neonates or newborn?
A. Yes, they are.
Q. And do you have any concern as the chief of pediatric infectious disease at the Children's Hospital in Chicago with using powdered infant formula with these babies?
A. We have really no concern about that. Again, the FDA reassurance is very helpful in that regard.
Q. And you've never had a case in your hospital in the 35 or 36 years that you've been there?
A. That's correct.
Q. Now, let's move to your review of Jeanine Kunkel's medical records in this case if you would. And please feel free to refer to your report. Do you have it with you?
A. Yes, I do.
Q. Okay. And, doctor, can you tell the jury what you found in

the medical history and the feeding history in connection with Jeanine Kunkel from her hospital stay April 14 to April 17 in 2008.

A. Well, she was fed initially Abbott's Similac ready-to-feed liquid until the morning of the 15th of April when her attending physician prescribed the NeoSure formula. And she was -- for the rest of her hospital stay at St. Luke's was fed NeoSure ready-to-feed liquid formula every 1 to 4 hours.

Q. Okay. So the doctor switched her to NeoSure?

A. Yes.

Q. When she was in the hospital, according to the records and the depositions that you read for purposes of your opinion and testimony today, did you see whether she came into contact with people at the hospital?

A. Well, of course, she was in contact with nurses, with family members, with staff of the hospital. Of course.

Q. And what about -- and family members you said?

A. Yes.

Q. Okay. And when she was discharged home, were there any doctor instructions?

A. The doctor instructions were for -- were for her to continue to use the NeoSure formula, and she was given some ready-to-feed packages as well as a large jar, bottle, of ready-to-feed as well as some powdered infant -- a can of powdered infant formula.

Q. And was there a recommend -- was there a instruction, a doctor instruction, for a well baby visit 3 to 5 days after discharge?
A. Yes, there was.
Q. And what's the purpose of a well baby visit 3 to 5 days after discharge from a birth hospital?
A. That's to verify that the baby is feeding well, that there's no new problems, that the examination shows no sign of any ongoing illness. It's also an opportunity to weigh the baby at that time.
Q. Now, when this -- Jeanine -- when Jeanine was born, she weighed 4 pounds, 14 ounces; is that correct?
A. Correct.
Q. And do new babies lose weight when they leave the hospital?
A. In the first 10 to 14 days of life, babies lose a substantial amount of weight. They're born with excess water. They get rid of that water, and they actually lose weight over the first 10 to 14 days normally.
Q. And you're referring to the food sources that she had in the hospital and then what she was given by the hospital when she came home. Why is that important to your review?
A. Well, that tells me what she was fed and what kind of formula she was receiving and in what format.
Q. Okay. And then did you learn what contact she had with what family members and friends when she got to her home after

discharge on April 17, the first week of her life?
A. Well, I know that there was a half brother or stepbrother at home. There were visits by the grandmother, great grandmother, I believe a grandmother's friend, several aunts, and several friends of the family.
Q. Okay. And one of the friends of the family was a Blake Verschoor who we've heard -- we've heard at the trial here. What was his occupation?
A. He was a landscaper.
Q. Okay. And is that -- being a landscaper, is that significant to you in any way in connection with this case?
A. Well, it's potentially important because enterobacter sakazakii is an organism that lives in the soil, and someone who is outdoors most of the time working with his hands in the ground is at greater -- greater likelihood of carrying the organism than someone who has no such contact at all with soil.
Q. And can you tell the jury about the baby's feeding history from when she arrived home on April 21 until -- I'm sorry, April 17 until April 21.
A. Yes. From that period of time the testimony is that she received the NeoSure ready-to-feed two-ounce bottles that were provided to her when she left the hospital.
Q. Okay. And after she finished those ready-to-feed, what was the next -- what was the next step in the feeding process at home from April 21 until April 23?

A. Yes. During that period of time she received the NeoSure ready-to-feed liquid out of the large bottle, I think 32-ounce if I'm not mistaken bottle, the ready-to-feed.
Q. And did you learn from documents in the case or depositions in the case where the ready-to-feed individual bottles and the 32-ounce bottle was stored before opening and feeding to the baby?
A. Yes. My understanding is that the testimony is that this -- these feeds were stored on the floor in the bab -- in the bedroom underneath the baby's crib.
Q. Okay. And also in Miss Surber's deposition, did you learn how she cleaned the bottles and the nipples for the 32-ounce feed, the ones that were not individual feeds but the ones that she had to make up from the 32-ounce bottle? Did you see that?
A. Yes. I believe she indicated that she had washed them, washed the nipples in hot, soapy water from the tap, and then rinsed them and let them dry in a rack and then put them in the cabinet in the kitchen.
Q. Okay. And what's the significance of pointing out where the mother stored the baby formula before opening it?
A. Well, my understanding is that the room where this was stored had a mold problem. There was some evidence of a sewer back-up in the house. There was a pet dog in the house. And because where mold is is generally damp conditions and damp conditions are important for the bac -- for growth of bacteria

and germs such as enterobacter, so to me that's of some significance. It raises the possibility that there's potential for contamination at that location.

Q. Okay. And then what happened in terms of the feeding history on April 23, 2008?

A. I believe in the evening -- the last -- the last feeding from the 32-ounce ready-to-feed formula was about 6 p.m. on the 23rd. And then beginning with the 9 p.m. feeding at that time, the mother, Mrs. Surber, was using for the first time the powdered infant formula.

Q. Okay. And what was the baby's symptomatology at 9 p.m. or around 9 p.m. when the mother first fed the baby powdered infant formula?

A. Well, that seems to be very close in time to when the mother was concerned that the baby was crying so much that she called her mother, the grandmother, to discuss the fact that the baby was crying and crying excessively.

Q. Okay. And did you review any contemporaneous medical records in connection with this event?

A. Yes.

Q. Okay. I'm going to show you Exhibit 1000G, doctor.

A. Yes.

Q. Okay? And you'll see that this is dated April 24, 2008, after the baby was taken to the hospital. What is significant in this medical record in terms of the symptoms that you're

talking about?
A. Well, the symptoms -- the reason the baby was brought to the hospital is fever and irritability, and this record says that the mother indicated that since the previous night the child has been fussier than normal and that then developed a fever later on and continued to be fussy.
Q. Okay.
A. As well as her feeding then also not being as normal -- not being normal.
Q. Okay. And then, doctor, I'm showing you Exhibit 1001A. This is from the Omaha Children's Hospital after Jeanine was taken there. And just in terms of the symptomatology, what is significant to you in this medical record?
A. Well, this is on the 26th, and it says that the baby was admitted again for fever and irritability two days ago and is described as being fussy all the night prior to admission and on the morning of admission had a fever.
Q. Okay. And now I'm showing you Exhibit 1000B, and I'd ask you to look at the -- and that's also from the Children's Hospital in Omaha. Can you see that, doctor?
A. Yes.
Q. Okay. And what does this medical record tell you in terms of the reason for admission?
A. Well, it says that she began not eating well in the 24 hours prior to her admission, then developed a fever.

Q. Okay. Now, are these medical records consistent with your opinion in this case?
A. Yes.
Q. Now, you saw some -- and are they consistent with the version of the mother, Megan Surber's, deposition testimony when she was first deposed in July of 2008?
A. Yes.
MR. RATHKE: Objection. Relevance. I had an objection, but I didn't have my mike on on relevance of the question of whether they're consistent.
THE COURT: Overruled. You may answer.
BY MS. GHEZZI:
Q. Doctor, do you -- in your normal -- in your normal practice, do you rely on contemporaneous medical records for treatment of your patients?
A. Yes, of course.
Q. Why do you do that?
A. Because those are records that are timely. They generally contain information that is very recent and families -- when a history is taken from a child, families recall the events, the recent events, very clearly. And that certainly seems to be in general much more reliable than what we can remember months or years later.
Q. And in your work for this case, I believe you said you reviewed deposition testimony, right, for the medical history?

A. Right.
Q. And did you review the medical history of the grandmother in this case, Mrs. Terrell?
A. Yes, I did.
Q. And do you recall what she said about the evening of April 23, 2008?
A. Yes. She indicated that her daughter had called her approximately 9 p.m. because the baby was crying so much and the mother was quite upset about the degree of crying.
Q. Okay. And do you recall from your review of the records in the case including the deposition testimony of the mother, Megan Surber, what the baby was doing at around 4 a.m. in the morning?
A. Yes. The mother indicated in her deposition that -- I think the term was really, really off-the-wall crying, so the baby clearly was extremely irritable and upset and crying at 4 a.m.
Q. Now, I'm -- you don't have the benefit of looking at it. I'm looking at it here, and it says getting really, really off-the-wall whiney. Does that change your statement at all?
A. Has the same meaning essentially, but it's whiney instead of crying.
Q. And so what was the feeding history throughout the night? We talked about the 9 p.m. feeding. What was the feeding history throughout the night down to 9 a.m. on April 24, 2008?
A. So the mother indicated that she gave a midnight bottle of

2-ounces and then again at 4 a.m. when the baby was extremely irritable and whiney fed the baby again at that time. And then I believe at 6 p -- 6 a.m. the child did not feed well and that at 9 a.m. the child did not feed at all.

Q. And do you recall any -- do you recall what -- how Miss Surber described the baby's condition at 9 a.m. in the morning in terms of what the sound of the cry was like at that point?

A. Something about a hyena-type crying, sounds of very impressive degree of crying.

Q. Okay. And then what happened next in terms of -- in terms of taking the baby to the hospital? When did that occur?

A. Well, the baby went to the hospital approximately 5:30 p.m. as I understand after not feeding really at all during the day.

Q. And the mother had tried to feed her, but the baby didn't eat; is that correct?

A. That's correct.

Q. Okay. When in your expert opinion did Jeanine Kunkel first begin exhibiting symptoms of meningitis, doctor?

A. I believe that the first symptoms were really present at 9 p.m. the evening of the 23rd.

Q. Okay. First of all, was there any suggestion in any medical record you saw that the baby had colic?

A. No, not at all.

Q. And does a ten-day-old baby get colic?

A. No. That's too early.
Q. And let's talk about your opinion and the reasons for why you say that the baby first began exhibiting symptoms of meningitis. How is it that meningitis progresses?
A. So I think we're all familiar with the concept of an incubation period when we're exposed to something, initially infected, but then don't develop symptoms until after a period of time. So in the case of meningitis, if it's an organism that's acquired orally, there are a number of steps that would have to occur biologically for the germ to actually be able to cause meningitis.
Q. Okay. And if the baby did not start exhibiting signs of meningitis until 4 a.m. in the morning or 9 a.m. in the morning, would that change your opinion about powdered infant formula here being the source?
A. No, it would not.
Q. Okay. Why not?
A. Because the steps that are required to develop meningitis after oral infection really takes days, three or more days, in order for that to develop.
Q. Okay. Let's tell the jury if you would how can E. sakazakii enter the body.
A. So E. sakazakii can enter the body through a mucosal surface such as a nose, throat, mouth, GI tract, gastrointestinal tract, or through the skin through an abrasion,

a cut, something of that kind, or through a medical device. All those are potential ways that E. sakazakii could enter the body.

Q. Can it enter the body on a pacifier?

A. Yes, it can.

Q. And is there anything in the literature that you've reviewed for this case that indicated -- that supports that conclusion of yours?

A. Yes. There's at least one circumstance where a pacifier has cultured out enterobacter sakazakii when cultures have been done.

Q. Can you tell the jury once -- let's assume the bacteria enters through the mouth here. Can you tell the jury what the process is that the bacteria goes through through the body, particularly of an infant ten days old about the size and weight of Jeanine Kunkel?

A. Yes. The -- so if a baby ingested an organism like E. sakazakii, the organism would pass into the stomach where the stomach acid would kill some of the organisms. Now, the stomach acid of a ten-day-old baby is not as strong as it is in older individuals, but still it has some effect.

And then the bacteria would move into the intestine and begin a process of settling into the intestine and then would -- in order to cause meningitis would have to -- some or one of the bacteria would have to be able to penetrate the wall of the intestine from the inside through the intestinal wall to

gain access into the bloodstream. And then once in the bloodstream, the bacteria has to begin to multiply.

Q. Okay. And this takes time; right?

A. This takes time. So in the multiplication of the bacteria, initially the bacteria has to adjust to its environment as in the bloodstream. And bacteria enter what is called the lag phase where they're stationary, they're not replicating, reproducing at all. Their numbers are constant. And this lasts several hours for E. sakazakii. At least in a test tube we know clearly it's about two hours in the human body because of the defenses that even a newborn baby has to try to fight -- ward off infection. It probably would take somewhat longer than two hours, but we're not certain of how much longer.

But then the bacteria after being in this lag phase move into what the microbiologists call the log phase when they start to multiply. And bacteria multiply by one cell, divides into two, and then two divide into four, four divide into eight, et cetera. And the replication time or the doubling time of the bacteria once they get their act together and start multiplying is somewhere in the one-hour range. The range in test tubes is anywhere from 35 minutes to 85 minutes for E. sakazakii. But if you average that, it's about an hour, 60 minutes, so that each 60 minutes there would be a doubling of the bacteria.

Q. Okay. So the log time which we're calling the doubling time for E. sakazakii in your opinion is 60 minutes.

MR. RATHKE: Objection.
A. Approximately 60 minutes.
MR. RATHKE: Leading.
MS. GHEZZI: I'm just re . . .
Q. Did you say it was 60 minutes?
A. Yes, approximately 60 minutes. Could be longer. Could be a few minutes shorter.
Q. Okay. And how many doubling times are necessary before there is enough E. sak, assuming it was ingested, until symptoms of an infection like meningitis appear?
A. So what's important -- to do that calculation which I have done, we have to realize first for a germ that gets into the bloodstream, for it to be able to pass into the central nervous system, into the meninges and where the brain is, to make that passage, there has to be between 100,000 and a million bacteria in every cc or milliliter of blood in the baby's body. If you do those calculations, it means there has to be -- there would be -- there would need to be somewhere between 18 million and 180 million bacteria in the baby's body as a result of all this duplication, multiplication of the bacteria in order for there to be a risk of transmission into the meninges to cause meningitis.
Q. And, doctor, because the testing indicated that there wasn't bacteria in this particular product, what did you assume when you were doing your calculation?

A. I looked at the historical information back from the '90s when -- when there were reports of positive cultures from powdered infant formula. The concentration of those organisms, those germs, was less than one organism per hundred grams of formula. If you calculate -- if you -- so I assume that -- for purposes of a calculation I assume that level. And that actually comes out to a small fraction of a single organism in the amount of powdered infant formula that the baby had ingested at 9 a.m., midnight, and 4 a.m.

So because that was just a tiny fraction of a single germ, I assumed -- I did my calculations assuming that there was one germ because a fraction of a germ can't obviously replicate. So just for purposes of the calculation, one germ would require 30 to 36 duplication times in order to reach the number of bacteria that would be required in the bloodstream to cause meningitis, to allow the bacteria to gain access into the central nervous system. So 30 --

Q. And how many -- let me just interrupt you there. And how many hours are 30 doubling times?

A. 30 doubling times are very closely 30 hours.

Q. Okay. And so for purposes of your calculation, you assumed a theoretical amount of bacteria.

A. Correct.

Q. Okay. Of one cell.

A. One cell, correct.

Q. And if the doubling period took 30 hours, how long would it take then for an infant to show -- begin to show signs of meningitis?

A. Well, so once there's been enough doubling in the blood of bacteria in the bloodstream to reach that high number of concentration of organisms, of germs in the bloodstream, the germs would have the potential to cross into the -- cross what we call the blood brain barrier that helps to protect against infections of -- like meningitis.

And once the bacteria gets to that location in the spinal fluid and in the meninges, there would be some additional doubling that would occur. And then there has -- really the number of germs in the spinal fluid has to reach a number, a critical number, that then leads to the white blood cells of the body and other kinds of defenses that the baby has to try to fight off this infection, to come into that area. And it's when those white blood cells actually arrive is when symptoms really develop of this kind of infection.

So all of this, all these steps, taking them all together, the best estimate is that it would take three or more days for bacterial meningitis to develop after oral ingestion of this kind of organism.

Q. Okay. And are you aware of any authority that is consistent with that opinion?

A. Yes, I am.

Q. And what is that?
A. There's a Bowen and -- I believe it's Bowen and Braden who have published an article where they estimated that it would take three or more days for bacterial meningitis to occur following the ingestion of an organism.
Q. And who do Bowen and Braden work for?
A. CDC.
Q. Now, are you familiar with Janine Jason's report in this case?
A. Yes, I am.
Q. Okay. And her opinion that the incubation time here could be less than 12 hours, maybe even as low as 7 hours?
A. Yes.
Q. Do you agree with that opinion?
A. Absolutely not.
Q. Why not?
A. Well, for the reasons that I stated. It's a complex process for bacteria to be ingested and go through the steps that I've outlined, reach the kinds of concentrations required for meningitis to become a possibility. This all takes days.
Q. And did --
A. Clearly days.
Q. Sorry, Dr. Shulman. Did she run any calculations or figures like you did?
A. Not to my knowledge, no.

Q. And she cites a study by -- maybe he's a doctor, but I'm going to say "mister" because it doesn't say here, Mittal, M-i-t-t-a-l. Are you familiar with that Mittal study from 2009?
A. Yes, I am.
Q. And can you describe just briefly what the study was about?
A. Well, that's a study of taking newborn rat pups that are about an inch long, weigh about five grams, and feeding them E. sakazakii and seeing if meningitis will result.
Q. Okay. Now, I'm going to show you -- zoom out. I'll get this right in a minute. Can you see that, doctor?
A. Yes, yes, I can.
Q. Okay. Thank you. Does this study and particularly the table 1 activity scores show a development of meningitis in these mice or rat pups in six hours?
A. They do not.
Q. Okay. And please explain why not for the jury, and feel free to use your stylus.
A. Sure. So this is -- this is a table of activity scores wherein it's common in studying rats and mice pups to try to assess their activity after you've done something to them. And the activity -- activity score is basically shown here in this footnote A where the animals are turned over on their back, and the normal animal jumps -- jumps right up, flips over on his feet, and runs around.
And so the animals were turned on their back and then

watched -- the observers watched what happened. And if the baby -- if the pups had normal activity, they were given a score of 5. If they turned upright but it took them a little bit longer than normal but under 5 seconds, they received a score of 4. If it took them even longer to turn upright from being on their back, as long as 30 seconds, they got a score of 3. And they got a score of 2 if they didn't turn upright at all and 1 if they were either comatose or death.

And you can see it's 6 hours after feeding these animals 10,000 germs of E. sakazakii, 6 hours later they all had normal activity. That is, you put them on their back, they bounced right up, they were all normal. That's not what an animal that has meningitis can do.

Q. And, doctor, it says there CFU and you're saying -- is that colony forming unit? Is that what that means?

A. Yes, CFU is colony forming units, and it means how many individual germs there were.

Q. Okay. And then -- so they were all normal at six hours; right?

A. Correct.

Q. And then what happened at 12 hours?

A. So at 12 hours, in 2 out of these 3 groups but not all 3 groups, the activity score dropped just a little. Again, the animal's put on their buck, turn upright within 5 seconds or less. And in those two groups, that was the average score

suggesting that maybe these animals were beginning not to feel so good overall. It doesn't necessarily mean they had meningitis at that time, but they're not feeling quite as spry by 12 hours.

Q. Okay. And, in fact, did Dr. Mittal reach a conclusion from his study about how long it took to cause meningitis within -- I mean how long it took to cause meningitis given this quantity of bacterial cells in these mice pups?

A. Yes. His conclusion in his article is that giving -- feeding these mice pups -- I think they were rat pups -- rat pups 10,000 individual organisms of E. sakazakii, that these -- some of the animals developed meningitis within 24 hours is his conclusion.

Q. Okay. And you're familiar with what Dr. Jason wrote in her report about why she thought you misunderstood the study because there was some blood in the brain tissue; correct?

A. Yes.

Q. Okay. Can you explain your thinking on that issue in connection with this study.

A. Yes. So what the investigators did in this particular study was to sacrifice animals at 6 hours, 12 hours, and 24 hours and grind up their various organs such as the brain, the liver, et cetera, and then culture them. And they present information to the fact that low numbers but some numbers of bacteria can be cultured from the various tissues that were

handled in this fashion as early as six hours.

The problem with this method is that isolating any organs such as the liver, the kidney, the brain, and grinding it up, there is always going to be bloodstream contamination of the tissues. And I believe clearly that the data that are expressed in that particular article reflect the presence of bacteria in the bloodstream rather than in the individual tissues which can be shown later on to be present but not at six hours.

Q. Okay. And, doctor, I'm going to hand you a copy of the Mittal article. I'm just going to ask you if there is anything in there that corroborates either by picture or graph your testimony here about the 24 hours.

A. Well, the investigators have shown sections of the rat brain and other -- this particular figure 5 is a rat brain and various portions of it at 48 hours after the feeding of these rat pups. They don't show any such pictures at earlier time points. Clearly by 48 hours there is evidence of meningitis that's developed.

Q. Okay. Thank you. Now, let's switch gears a little bit in terms of any other reasons why you have concluded that Abbott's infant formula could not have caused the infant's infection. Did you review the statements that the mother made to the investigators at the time of the incident?

A. Yes, I did.

Q. Okay. And I'm going to put up for you Exhibit 2012.

A. Yes.
Q. Okay. And, doctor, what was significant, if anything, in that particular document to you?
A. Okay. Well, down here at the bottom under comments regarding the home preparation of the powdered infant formula, it says boiled the water and let come back to room temperature and then added the formula mix and then reheated to a boil and cooled it.
Q. And cooled to maybe room temperature?
A. I can't read that. Cooled to room temperature, yes. So the fact -- what's significant to me is that she indicated that after adding the formula, the powdered formula, to the water she reheated it again to a boil and then cooled it before using.
Q. Okay. Now, if she only did that for the 9 p.m. feeding on April 23, would that change your opinion at all about incubation time or infectious dose here?
A. No, not at all.
Q. Why not?
A. Well, if -- if she -- if she boiled the formula after mixing it, any bacteria that might have been present even though I don't believe there was any present in the powdered infant formula would be killed by boiling. And that would make the first potential exposure to powdered infant formula that wasn't boiled possibly at midnight.
Q. Okay. And would it make any difference to you if the

boiling occurred in a water bath, in other words, if there was a pan of water that was heated on the stove and the bottle itself was placed in it and then heated and the water around it boiled?
A. No, because -- so what we know about how quickly high temperatures kill off the bacteria, you can heat something to a boil for a s -- formula, for example, that's mixed, you can heat that to a boil for as short as a second, and it will kill all the bacteria. But at temperatures leading up to boiling -- so, for example, at about 150 degrees or 70 degrees Centigrade, 150 degrees in Fahrenheit -- in 15 seconds the bacteria will be killed. And at -- so as -- as the bottle is being warmed, it will -- even if everything inside the bottle doesn't boil, it's going to be exposed for many seconds to as long as a minute or more to high temperatures above 70 degrees Centigrade or 150 degrees Fahrenheit.
Q. In any --
A. So -- so that will kill off bacteria within a 15-second exposure or less.
Q. Fifteen seconds?
A. Fifteen seconds. And as the temperature gets higher, the exposure time that's needed to kill bacteria drops off.
Q. Okay. Now, doctor, in your methodology when you're looking at the possible sources of infection of Jeanine Kunkel, for the bacterial meningitis of Jeanine Kunkel here, did you consider some possible sources in the Kunkel family home?

A. Yes, I did.
Q. Okay. And I'm going to put up for you a summary document. Do you see the sources on the bottom there?
A. Yes.
Q. It's a little hard to read right there but . . .
What items and environments could have been direct sources of E. sak or cross-contamination of Jeanine Kunkel's -- either her ready-to-feed liquid infant formula feedings or anything else that she came into contact with?
A. Well, as I indicated earlier, this is a very ubiquitous type of germ. It's found in lots and lots of places, and among the places it's found are -- is people, so the people the child -- the baby was exposed to. The father had a respiratory infection we know and was coughing up sputum. The other members of the immediate family, the extended family, and all the visitors, any of those could be potential sources just like any of us today could be colonized with enterobacter sakazakii and not know it and potentially spread it by cross-contamination, by touching something, a surface that someone else touches.
Q. Okay. Is there anything on that summary list that you disagree with in terms of it could be a -- some possible source of E. sakazakii in the Kunkel home?
A. No. Any of these, people, foods, furnishings and appliances, other items, environmental items, baby items, animals, insects, any of those could be a potential source of

this very common and ubiquitous germ.
Q. Were you able to rule out any of those -- I'll put it back up; I'm sorry -- any of those possible sources of E. sak in the Kunkel family home?
A. No, I was not.
Q. And why not?
A. Very, very few environmental-type cultures were obtained. They were obtained something like 12 days after the fact. And they -- the only environmental cultures that were obtained was water from the kitchen faucet, the faucet itself, the aerator, and the counters on either side of the kitchen sink.
Q. Okay. And even the water that was tested by the CDC, do you know what the results of the water test from May of 2008 were?
A. Well, I know that there were bacteria present in the water supply, but there was no identification of the enterobacter sakazakii at that time.
Q. And as you pointed out, that was taken -- that water sample was taken some time in May 2008, like 11 or 12 days after the illness began?
A. That's correct.
Q. Okay. That doesn't say anything about the water content or the water quality on April 23 or prior to that, the week of April 17, 2008, does it?
A. No, it does not.

Q. Now, in your report you noted -- and it is in the demonstrative right here, the summary right here -- that Jeanine's father had an infection at the time; correct?
A. Correct.
Q. Okay. And did you look at medical records of Troy Kunkel in assessing his medical situation?
A. Yes, I did.
Q. Okay. And can you tell -- they've heard a little bit about this before not from you and you haven't heard it, but can you tell them a little bit about what was significant to you about Troy Kunkel's medical history and his medical condition on or about April 2008?
A. Yes. So what's significant about his medical history is that he is an immunocompromised person. He had his spleen removed surgically when he was a child. When your spleen is removed, that takes away a good component of your immune system. In addition, he has diabetes which is a metabolic disease which increases risk for infection.

So he's an immunocompromised person who was admitted to the hospital with fever, vomiting, cough, body aches. He was coughing up grayish-type sputum. The doctors taking care of him, because he had body aches and neck aches, were concerned a little bit about the possibility of meningitis, but they ultimately concluded that he had pneumonia, and that's what the medical records indicated.

Q. And was he hospitalized not just on -- was that on or about April 25, 2008?
A. Correct.
Q. And was he hospitalized earlier that month as well?
A. Yes, he had been in the hospital several weeks earlier with complaints as well.
Q. Okay. Now, the vomiting and the sweats and that sort of -- that sort of symptom that he was showing on April 25, is that consistent with diabetes, maybe uncontrolled diabetes?
A. Yes, it could be certainly. Uncontrolled diabetes would give a lot of vomiting and fever, sweats.
Q. Okay. Was he ever tested for E. sakazakii in the hospital?
A. He was not tested for that at all.
Q. Was anyone who came into contact with Jeanine Kunkel in terms of the medical records that you've seen and all the documents in this case ever tested for E. sakazakii?
A. No.
Q. And, doctor, then can you rule those individuals out as a potential source?
A. No, they can't be ruled out as potential source.
Q. Okay. Now, is it -- what's your opinion about whether or not Troy Kunkel, the father, and Jeanine Kunkel could have developed an infection from the same source?
A. I think it's quite possible that both of them -- first of all, Mr. Kunkel might have had a C sa -- an E. sakazakii

infection. We don't know that for certain because he was not cultured. But if he did, he and the baby could both have acquired it from an environmental source.

Q. In the home.

A. In the home.

Q. Okay. Okay. And, doctor, switching to another topic, do you agree with Dr. Jason's opinion that there is an association between powdered infant formula use and E. sak meningitis, particularly in sporadic or isolated single cases like this one with Jeanine Kunkel?

A. Yes, I do have an opinion, and my opinion is that there does not seem to be an association in the sporadic cases like this of this kind of infection.

Q. And how many outbreaks as opposed to sporadic, isolated cases have there been in the United States that have been reported?

A. There are only two small outbreaks that have been reported ever.

Q. Okay. And in your opinion was her -- was her analysis based on any valid epidemiological method?

A. I don't believe so, no.

Q. Okay. And what is wrong with the method that she used in your opinion?

A. Well, she -- a number of things, but she basically relied upon reports of cases of invasive enterobacter sakazakii

infection in infants and simply tabulated how many of them had what kind of feeding. She did not -- to include cases -- to implicate cases as being related to powdered infant formula, she did not require any kind of positive culture from the formula or anything of that sort or any other feeding. So it's very anecdotal. It's nonscientific, and it's not the way to really prove an association with a particular food stuff.

Q. And did you have occasion to read the comments of the reviewers, some of the reviewers, who critiqued her Pediatrics article?

A. Yes, I did.

Q. And what's your recollection of what you read?

A. My recollection is that --

MR. RATHKE: Objection. Hearsay.

THE COURT: Sustained.

BY MS. GHEZZI:

Q. Did you rely on -- to form your opinion about her method -- her methodology and what she did with her Pediatrics article, was it important for you to review the criticisms that the reviewers had made?

A. It was not essential for that purpose. Found it very interesting because I think they made some very interesting points.

MR. RATHKE: Your Honor, I think he's answered that.

Q. And what points did they make?

MR. RATHKE: Same objection.
THE COURT: Yeah.
MS. GHEZZI: Your Honor, he's not stating it. He's not saying what was written. He's saying --
THE COURT: Yeah, but, see, we're in a foundation problem.
MS. GHEZZI: Okay.
THE COURT: So you need to lay the foundation before we can get into the substance of it.
MS. GHEZZI: Okay. Let me --
BY MS. GHEZZI:
Q. I'm just going to ask you. What do you think is wrong with her epidem -- let me ask you this. What would a proper epidemiological study look like?
A. Well, the best kind of epidemiologic study would be a prospective cohort of babies that are followed prospectively, not looking back on what happened but looking forward with a group of babies who can be assessed going forward to assess various risk factors and to try to identify risk factors that might be associated with this particular rare infection.
Q. And so what would this type of study require an investigator to survey?
A. You would survey a group of newborn babies -- numbers would have to be fairly large -- and survey them with respect to what kind of medical problems they develop over the first several

months of life and what risk factors they've experienced during that period of time such as feeding type A, feeding type B, and other kinds of risk factors in their environment.

Q. And has this kind of study ever been done in connection with E. sakazakii?

A. Yes, there has been one such study that involved, I think, 10,660 low-birth-weight infants. This was performed at the National Institutes of Health. They followed these babies forward for a period of time. And out of those 10,660 babies, there was 1 baby who developed an infection with E. sakazakii in the bloodstream, not meningitis, but it was an invasive infection in the bloodstream. And that baby had not received any powdered infant formula. No other babies developed this infection in that study.

MS. GHEZZI: One moment, Your Honor?

THE COURT: Sure. Miss Ghezzi, would now be an appropriate time for us to take our recess?

MS. GHEZZI: Yes, yes, it would.

THE COURT: Thank you.

MS. GHEZZI: Thank you.

THE COURT: Members of the jury, it's 12:15. We'll be in recess until 20 minutes to 1. Thank you.

(The jury exited the courtroom.)

THE COURT: Thank you.

(Recess at 12:16 p.m.)

THE COURT: Thank you. Ready to have the jury brought in?

MS. GHEZZI: Yes, Your Honor.

(The jury entered the courtroom.)

THE COURT: Thank you. Please be seated.

Miss Ghezzi, you may continue your direct examination.

MS. GHEZZI: Thank you, Your Honor.

BY MS. GHEZZI:

Q. I just want to go back over one area. Dr. Shulman, is it possible for babies who eat just ready-to-feed formula to get infected with E. sak?

A. Yes, it would be possible, yes.

Q. Okay. And have you seen that in the literature?

A. Yes.

Q. Okay. And how is it possible? How does it happen?

A. Well, it happens because in preparing ready-to-feed bottles, there's a lot of hands-on activity, lot of steps that have to be taken in terms of mixing -- putting the nipples on the bottles, and that's done with hands. And without good hand washing, for example, and other possible contamination in circumstances, there could be inoculation of organisms on to the nipple.

Q. And have you seen situations where a nipple has been -- a bottle nipple has been inoculated with -- as you would say, with E. sak bacteria?

A. Yes, there are positive -- reported positive cultures in that circumstance.
Q. Okay. And if the bottles are made up ahead of time and placed in the refrigerator, can there be cross-contamination somehow?
A. It's possible if one goes into the refrigerator, touches other things, and then touches the bottle, that would be one possibility, yes.
Q. And what if there are other foods in the refrigerator at the same time like fresh vegetables or meats?
A. Those are things that can be colonized with this particular germ, but there would have to be touching of a surface that was cross-contaminated by a particular food, let's say, earlier and then a bottle being put in the same location and getting -- for the potential for then getting on hands and contaminating the nipple.
Q. And is it possible for babies who are fed exclusively breast milk to get an E. sak infection?
A. Yes, there are a number of those reported, yes.
Q. And switching gears just slightly, what kinds of illnesses do adults with E. sakazakii infections get?
A. Well, adults get a wide variety of infections that would include pneumonia, bloodstream infections, wound infections, bile infections. This kind of organism is an opportunistic bug, and it can cause a wide spectrum of infections.

Q. Okay. And so the fact that Troy Kunkel was diagnosed with pneumonia, does that allow you to rule him in as a possible person who was colonized with E. sakazakii?
A. He is possibly colonized, but we don't know for certain without a culture.
MS. GHEZZI: Thank you. I have no further questions, Your Honor.
THE COURT: Thank you.
Mr. Rathke, you may cross-examine.
MR. RATHKE: Thank you.

CROSS-EXAMINATION

BY MR. RATHKE:
Q. Now, doctor, the fact that the testing of the cans, the open can and the unopened cans, for E. sak was negative was a pretty important factor that you considered; correct?
A. Correct.
Q. In fact, you thought it was so important that on January 6 you shared that information with the readers of the Sioux City Journal; correct?
A. I have no knowledge of that, sir.
Q. Do you ever comment on newspaper articles?
A. I'm sorry. Do I comment on newspaper articles?
Q. An article in the newspaper and then there's readers' comments?
A. Like a letter to the editor?

Q. Not a letter to the editor. A comment to a newspaper article.
A. Not to my knowledge. I don't know what you're talking about.
Q. Well, there's a person named Dr. S. Your name's -- your first name is Stanford; right?
A. Correct.
Q. Last time is Shulman.
A. That's correct.
Q. Right? And he starts out with saying if anyone is familiar with this case -- and you, of course, by June -- by January 6 you were familiar with the case.
A. January 6 of this year?
Q. Yes.
A. Yes, I certainly was familiar with the case.
Q. -- they know that no bacteria was found in any one of the cans. That's what the comment was from Dr. S. in the Sioux City Journal of January 6, and that's a fact that you knew on January 6 as well; correct?
A. I knew that, yes, as did you, right, so everybody -- yes. Anyone involved in this case knew that.
Q. Do you know anybody involved in the case that would identify themselves as Dr. S.?
A. No.
Q. You go on to say or somebody goes on to say -- Dr. S. goes

on to say it is very obvious this family's out for financial gain. Did you write that?
A. I absolutely did not write that, sir.
Q. Do you have any idea who Dr. S. would be who is familiar with the case and on January 6 knew that bacteria was not found in any of the cans?
A. I have no knowledge of what you're talking about, sir.
Q. Okay. I'm going to set before you your appendix B and a number of articles that you make reference. Please keep them in order because I think that would be easier.
The first article is -- I don't know how to pronounce this, but it's Beuchat, B-e-u-c-h-a-t. He wrote an article on E. sak in 2009 in the International Journal of Food Microbiology. Do you see that?
A. Yes.
Q. And you do reference that in your report; correct?
A. I believe so.
Q. And do you have the article? Are you looking at the front page of the article now?
A. Yes, I am.
Q. Do you see where -- and I underlined this just so -- to make it easier for everyone. Do you see that on the first page Dr. Beuchat says reconstituted powdered infant formula and powdered milk have been the most common vehicles implicated in neonatal E. sakazakii infections? Do you see where it says

that?
A. Yes.
Q. Do you agree or disagree?
A. I'm not sure I agree with that because he goes on to talk about other unidentified sources of the pathogen have been involved in cases of children and infants and adults. So it's incomplete as a single sentence.
Q. Well, it's a sentence that he starts out that paragraph stating, that reconstituted PIF and powdered milk have been the most common vehicles implicated in neonatal C. sakazakii infections. That's what he says; correct?
A. That's what he says, and he goes on and clarifies or comments upon -- expands is the right word, expands upon that in that subsequent paragraph.
Q. All right. Let's take that. The next sentence says other unidentified sources of the pathogen were involved in cases of infections in infants, children, and immunocompromised adults having underlying medical conditions. That's the next sentence, isn't it?
A. Correct.
Q. All right. Do you agree with both of those sentences?
A. In general I do but with all the qualifications -- qualifiers that follow beyond that, yes.
Q. All right. One of your other sources is Bowen and Braden, and I think what you're referencing is chapter 4 which they

authored in this best-selling book called Enterobacter Sakazakii; right?
A. I believe so.
Q. Now, I only have one book, but I'm going to read portions to you and ask you if you agree or don't agree.
MS. GHEZZI: Hearsay, Your Honor. Oh, he didn't read it yet. I was just going to say hearsay.
MR. RATHKE: Maybe I could lay better foundation.
THE COURT: That would be -- that would be helpful.
BY MR. RATHKE:
Q. That is the -- I mean, we're on the same page. That's the article and the reference that you use as a reference in your report; correct?
A. It's correct if you're on the page that starts -- the article or chapter that starts on page 101.
Q. Great. I am. And then you alluded to that chapter in your -- that was the chapter you were referring to in direct examination; correct?
A. I believe so.
Q. Okay. I'll read this. And if you think I'm reading it wrong, I'd be happy to hand it to you.
MS. GHEZZI: I have a copy if you want to give -- do you want to give him a copy?
MR. RATHKE: Sure.
Q. I think -- look at page 106. Do you see there's a heading

Reservoirs and Transmissions?
A. Yes.
Q. And it states there to start out with the paragraph after that heading many possible sources and modes of transmission for E. sakazakii infections have been debated. However, the only vehicle that has been epidemiologically and microbiologically associated with infection is powdered infant formula or the equipment used to prepare it. Do you see where it says that?
A. Yes.
Q. Do you agree with that?
A. Well, as far as it goes, not exactly because there really are reports of positive cultures from pacifiers, from artificial nipples that have been also identified.
Q. Isn't it a fact that no case of neonatal E. sakazakii infection has been proved to be from any other cause other than powdered infant formula?
A. I don't believe that's the case. There are lots of environmental positive cultures including from, as I said, pacifier and nipples.
Q. You referred to Bowen and Braden in your discussion about incubation and carriage which is at page 108. Do you want to find that? Do you have it in front of you?
A. Yes.
Q. What it really says there is because the route of exposure is generally unclear at the time of infection, the incubation

period is unknown. That's what it says in that one sentence; correct?
A. Correct.
Q. And it goes on to say, however, in outbreaks associated with PIF, infants began -- or illness began as soon as three or four days after initial exposure to the implicated formula product. That's what it says; correct?
A. Correct.
Q. Another source that you use is the article by Dr. Friedman in 2009. Do you have that in front of you?
A. Yes.
Q. On the first page underlined it states globally about 120 to 150 cases have been reported in the high-risk group of infants up to 2 months of age. Do you see where it says that?
A. Yes.
Q. Do you agree with that?
A. Globally, yes, I think that's about right.
Q. It also says at the bottom of that column in the U.S.A., incidences of 1 cronobacter infection per 100,000 infants, 8.7 per 100,000 low-birth-weight neonates, and 1 cronobacter infection per 10,660 very-low-weight neonates have been reported. Do you see where it says that?
A. Yes.
Q. Do you agree with that?
A. No, I don't. I think the incidence in the U.S. is closer

to one cronobacter meningitis per million babies as I indicated.
Q. So although you cite Dr. Friedman as a reference, you don't agree with the statistics that she sets out in her article?
A. Well, I certainly wouldn't agree with every sentence in every article that I've cited because they're not -- there's inevitably going to be some misstatements or something that's not quite right.
THE COURT: Well, that wasn't the question he asked you, was it?
THE WITNESS: Could I have the question back then, please?
THE COURT: Sure.
MR. RATHKE: Could you read it back, please?
(The requested portion of the record was read.)
A. So what I -- what I should say here is that I realize that she's talking about all cronobacter infections, not simply meningitis. The estimate of one per million is -- per infants is related to the cronobacter meningitis. There are some other cronobacter infections, so if you calculate -- include those in the calculation, this is probably correct.
Q. Are you saying that her statistics are different from your belief because she's including cronobacter infections that are not meningitis?
A. Correct. This is referring to incidence of cronobacter infection, not simply meningitis. That's why the number's

different.
Q. If you'd go to -- I put a tab in your copy because the pages don't always come through. But you see where the tab is, there's some underlining underlying text. Do you have that in front of you?
A. Yes.
Q. And there Dr. Friedman says the main source of neonatal cronobacter infections, comma, contaminated powdered infant formula, comma, has been ascertained in various outbreaks and single cases. Do you see where it says that?
A. Yes.
Q. Do you agree with that?
A. Not completely, no, sir.
Q. The -- then she goes on to say at that point the environment in powdered infant formula processing facilities has to be regarded as potentially contaminated. Do you see where it says that?
A. Yes.
Q. Do you agree with that?
A. Well, I guess I do agree with that. That's why there's lots of culturing and monitoring of processing facilities.
Q. Okay. Manufacturers of powdered formula for infants and young children should control the microbiological hazards in the raw materials during the whole processing chain and of the final products according to international recommendation and European

legislation. Do you see where it says that?
A. Yes.
Q. Do you agree with that?
A. Well, I don't think -- partially. I don't think the European legislation refers to the United States. But Dr. Friedman is writing from Germany, so that -- that would be relevant to the Europeans for sure.
Q. Another publication that you cite as a reference is a article by Susan Joseph and Stephen Forsythe entitled Prominence of Cronobacter Sakazakii Sequence Type 4 in Neonatal Infections. That is an article you rely upon; correct?
MS. GHEZZI: Objection, Your Honor. Beyond the scope. We didn't do anything about sequence type in the entire direct examination.
THE COURT: Overruled.
Q. Am I correct, doctor?
A. I believe it was cited, yes. Let me check.
Q. And then on the second page where I put the tabbing of that article and also did some underlining, there's a sentence that starts out the seven household genus for MLST analysis -- and then I'm going to stop right there and ask you do you know what they mean, what the two doctors mean when they say that?
A. Sure.
Q. What do they -- what's that mean?
A. So they're talking about multilocus sequence typing which

is a modern molecular typing method for bacteria. And the bacteria are typed by assessing the genes for each germ that one is going to try to do this kind of analysis. The -- when you set it up, you need to select certain housekeeping genes which are genes that the bacteria needs in order to just survive and replicate. And those genes are sequenced. And then you can use those genes. You can analyze those genes in clinical strains or laboratory strains of the particular organism you're dealing with in order to try to divide them up into categories.

Q. Okay. Thank you for the explanation. The sentence actually says the seven housekeeping genes for MLST analysis are not virulence related. It goes on to say but a large proportion of severe neonatal infections were caused by a single sequence type. Do you see where it says that?

A. Yes.

Q. And, of course, the sequence type they're talking about is -- the subject of the article is ST4; right?

A. Yes.

Q. Do you agree with their opinion with respect to the ST4 sequence?

A. I agree with their conclusions that many --

Q. Do you -- I didn't ask you that; okay?

A. I'm sorry.

Q. What I asked you is do you agree with the sent -- the part of the sentence where he said a large proportion of severe

neonatal infections were caused by a single sequence type? That's what the sentence says. And that makes reference to sequence type 4; correct? And what I want to know is if you agree with that.

A. Yes, I agree that their data showed in this select group that one sequence type predominates. But this doesn't encompass all infections, of course.

Q. The next article that I'd like to show you that you relied upon is another article by the same Professor Joseph, and that's entitled Diversity of the Cronobacter Genus As Revealed By Multilocus Sequence Typing. Do you have that in front of you?

A. I do.

Q. Now, some of these articles do people the favor of making a synopsis to start with, and this one does, and you see that, don't you?

A. Yes.

Q. And the last sentence of the synopsis says the predominant species from clinical sources was found to be C. sakazakii. C. sakazakii sequence type 4 was the predominant sequence type of cerebral spinal fluid isolates from cases of meningitis. Do you agree with that statement by Dr. Joseph and others?

A. Well, I'm trying to find it here. I'm sorry to delay, but I'm trying to find whether they actually present the numbers so that I can answer your question. I think it's going to take more time to go through this and really try to analyze this with

that -- with respect to that specific point.
Q. All right. You can set that aside. Why don't you go to the one that I -- the Joseph article that I kind of interrupted you, and I'm feeling bad about that because I think you were going to talk about a conclusion of their article on sequence type 4, the earlier article. And in the synopsis in that article, one of the -- it's a short one, and one of the sentences says C. sakazakii ST4 appears to be a highly stable clone with a high propensity for neonatal meningitis. Do you see where it says that?
A. Can you give me a hand here? It's not underlined or anything, so I'm not sure where that is. Yes, that's their conclusion. If you look at their table, it's pretty much supportive of that.
Q. Okay. The next article is Mittal, and he got mentioned on the subject of rats, and what I've got before you is an article you relied upon entitled Brain Damage in Newborn Rats, et cetera, by Professor Mittal in 2009. And he also has a synopsis. And the second -- third sentence in the synopsis which I've underlined says here we demonstrate for the first time using a newborn rat model that outer membrane protein A, OmpA, expression is important for the onset of meningitis by E. sakazakii. Do you see where it says that?
A. Yes.
Q. Do you agree with that?

A. I think this article did show that in the rat model.
Q. All right.
A. We don't know what relates to people but certainly in the rat model.
Q. And the last article I'm going to show you is by Eva -- Dr. Eva Kucerova.
A. Kucerova I believe, yes.
Q. Kucerova, and also joined by Dr. Joseph and Dr. Forsythe. This was in the 2011-- in 2011 in Quality Assurance and Safety of Crops and Foods, and it's entitled The Cronobacter Genus Ubiquity and Diversity, and that's an article that you relied upon.
A. Yes.
Q. If you go to the page that's tabbed and under the heading source -- sources of infection, it states, does it not, while the source of contamination in cronobacter-related outbreaks has not always been confirmed, comma, breast milk substitutes, paren, one group of powdered infant formula products, close paren, have been epidemiologically or microbiologically established as the source of infection in a number of cases. Do you see where it says that?
A. Yes.
Q. Do you agree with that?
A. I think there are a number of cases where there's been that connection made, yes.

Q. Then on the -- under the same heading, the writers state that the neonate has an immature immune system and low intestinal microflora density. Consequently, if a large number of cronobacter cells were ingested, they would not be outcompeted by the resident intestinal flora. Following invasion of the intestinal cells, the lack of the developed immune system could make the neonate more prone to systematic infection. So far do you agree with me or with the article?
A. I'm sorry. I didn't see where you were. Now I find it. Let me read it.
Q. I started with the neonate has an immature --
A. Yes.
Q. And I stopped with systematic infection.
A. Yes, I agree with their statement that -- with this statement that it could make the neonate more prone. It doesn't -- they can't state that it does. This is a hypothesis that they are promoting -- proposing.
Q. Well, do you agree with the hypothesis?
A. I think it's a reasonable hypothesis, but it's not proven.
Q. Okay. The next sentence says no infectious dose has been determined for neonates. Do you see where it says that?
A. Yes.
Q. Do you agree with that?
A. Yes, I think that's correct.
Q. Abbott has employed you as an expert in other powdered

infant formula cases?
A. One other I believe.
Q. And what's your hourly rate for testifying here today?
A. $800 an hour for testifying.
Q. I want to cover a couple things you said in your testimony, not a whole lot but just a few, if I can figure out what I wrote.
You discussed the WHO report from 2008 which had a table in it. Do you remember that discussion?
A. Yes.
Q. Now, it's true, is it not, that the WHO report in 2008 was devoted to the subject of what's called follow-up formula; correct?
A. I don't recall specifically that. I'd have to review that.
Q. Well, the tape -- I mean, it's a -- it's a blue book like this. Did you ever see a blue book like this?
A. I've seen Xerox pages out of it.
Q. Okay. All right. And when you were provided those pages, did they provide you with the entire 2008 WHO report?
A. I believe so.
Q. Okay. And do you recall that it was entirely devoted to follow-up formula?
A. I don't recall that term specifically, but that may be correct.
Q. Follow-up formula, of course, is formula for older children

like six months and older; correct?
A. I'm not sure I recognize that term specifically to mean that.
Q. Do you know if it means something else?
A. I do not know.
Q. All right. When you described the findings in that table, you were very careful about saying majority of isolates, not majority of children or cases; right?
A. Well, that table included -- as I recall, the table I was referring to included the number of bacterial isolates in clinical microbiology laboratories in the UK and I think Wales. And those isolates that were obtained from many different laboratories and hospitals were broken down by age of the individual from whom the cultures were obtained. That's the table I was referring to. And the point I was making is that the large majority, the very large majority, of those isolates are really from adults and older children rather than from newborns.
Q. Because adults can get cronobacter infections; correct?
A. Absolutely, sure.
Q. Doesn't kill them.
A. It could. Immunocompromised host, absolutely.
Q. Rarely kills them, doctor. Very rarely kills an adult. It makes them sick; right?
A. It makes them sick, very sick, potentially very sick and

potentially fatally sick.
Q. You criticized the epidemiological study and conclu -- well, the study that Dr. Jason provided. Do you recall that?
A. Yes.
Q. And you may know that on Monday, Tuesday, and Wednesday she was here in court testifying about it.
A. Yes.
Q. As I understand your viewpoint on this, the only study that would have any validity would be one that's prospective and cohort.
A. That would be the best kind of study to do, yes, sir.
Q. And that means that you could start like in 2014. That'd be year -- I don't know what -- the technical term, but that'd be year zero, and then you would go forward in time instead of looking backward in time.
A. Correct.
Q. And what you'd do is you'd select a whole bunch of people presumably at random, and then you'd follow them for a number of years.
A. Well, depends what question we want to ask. That would not be correct if the question being asked is what's the frequency and what are the risk factors associated with neonatal or infant enterobacter sakazakii infection. If that's the question, then the patients would only need to be followed for a matter of months, not years and years.

Q. Well, the patients that you're -- the people you're talking about are the people that contract the disease; correct?
A. No, sir. You're talking about a cohort study prospectively would be to recruit a number of newborns because that's the population one is concerned with and then prospectively follow that group of newborns for as long as the study designers felt would be appropriate such as till they're four months old, three months old because it would be my -- my best effort to do that because that's the period at which there's concern about cronobacter meningitis in particular in young infants.
Q. Well, given the rarity of this disease, four to six cases in the United States in a given year, if you took a whole bunch of infants, it'd be blind luck if you even had one of them in that group; correct?
A. Well, you'd have to choose your group's appropriate size. That's correct.
Q. Now, as an epidemiologist, what you do is you're a hospital epidemiologist; correct?
A. Correct.
Q. And one of your very particular expertises is in the area of strep throat -- or strep?
A. I do a lot of research and clinical work on strep, that's correct, strep throat.
Q. And strep is often an issue in a hospital?
A. Not so often fortunately.

Q. At any rate, the epidemiological work you do is within the confines of the hospital; correct?
A. Well, it's within the confines of the hospital and patients in the hospital because very frequently I'm involved with patients in whom there's an epidemiologic question as to where did this infection come from, how did the child get sick, et cetera.
Q. I'm going to bring up Exhibit 148. This was a -- something that was shown to you during your deposition, and it's a health professional letter on E. sak sent from the FDA to health professionals and sent in 2002, actually twice, one in one version and then one in another version. You don't recall ever seeing that, do you?
A. I do not recall seeing that. I don't recall seeing that at my deposition either, but I may just be misremembering.
Q. Yeah. And your hospital is not -- as I understand it, it's not a birth hospital. It's a hospital where babies are taken when they get real sick.
A. Well, we're next door to a birth hospital, but we are not a birth hospital. We take care of sick children.
Q. And you have a NICU unit.
A. We do.
Q. Is your whole hospital a NICU unit or just a portion of it?
A. Just a portion of it.
Q. So you as a person within -- you know, a hospital

epidemiologist in the NICU unit, you don't recall ever getting this letter from the FDA with respect to the use of powdered infant formula for NICU babies.

A. I don't recall seeing that, no, sir.

Q. You testified that powdered infant formula's given to NICU -- NICU babies today in your hospital.

A. Correct.

Q. Isn't it a fact that what you're talking about is human milk fortifier where a baby is so premature that her mother -- that the baby's mother's breast milk does not provide adequate nutrition and what is given to babies in that situation is a human milk fortifier which they get along with breast milk; correct?

A. That would be partially correct. That would be one aspect. The other aspect is what I referred to earlier about babies who have a metabolic disorder that need a specialized powdered -- a specialized diet that comes as a special powdered infant formula.

Q. And it is true, is it not, that they haven't figured out how to make ready-to-feed human milk fortifier? The only way those babies can get the fortifier is the powder.

MS. GHEZZI: Objection. Lack of foundation. No testimony about human milk fortifier and how it comes.

MR. RATHKE: Well, there may be in a minute.

THE COURT: Just a second. Overruled. You may

answer.
BY MR. RATHKE:
Q. Do you want the question again?
A. Yes, please.
Q. Isn't it a fact that in the case of human milk fortifier which is needed for these premature babies, you know, very early babies whose mother's milk is not sufficient, that the only way they can get the human milk fortifier is in powdered form because there is no alternative ready-to-feed?
A. I'm sorry. I don't under -- I don't know if that's true or not. I do not know.
MR. RATHKE: You can take that off.
Q. Do you agree with the notion that with respect to E. sakazakii infections low-birth-weight babies are at a greater risk than healthy term babies?
A. Well, that's an interesting question because that used to be very clear and it's not so clear anymore because there are increasing reports of full-term babies so that the dominance of pre-term babies doesn't -- no longer seem to exist.
Q. Would you agree that no one knows the incubation period for human babies?
A. Well, no one knows for certain, but I think that the estimates -- the best estimates are that it'd be three to four days or more in terms of oral ingestion of the organism and the steps required as I outlined for development of meningitis.

Q. Would you agree with respect to the incubation period for human babies you don't think anyone knows precisely; correct?
A. Yeah. No one knows precisely, but estimates are about three or four days minimum.
Q. Now, in your report and your testimony you talked about infectious dose, and you had a -- I don't know what you'd call it -- a theory or a hypothesis with respect to the amount of E. sak that might have been in the powdered infant formula if, in fact, it contained E. sak. Are you following me?
A. Yes, I think so.
Q. Okay. And your basis for that is the fact that E. sak was found at a low level in the 1990s.
A. Correct, extremely low level, yes, sir, that's correct.
Q. Actually you base that on information not only in the 1990s when nobody cared but also in the early 2000s; correct?
MS. GHEZZI: Objection, Your Honor. Argumentative, when nobody cared.
THE COURT: Sustained. Why don't you rephrase the question.
MR. RATHKE: Yes, Your Honor.
BY MR. RATHKE:
Q. Actually in your report and what you referred to is amounts found in powdered infant formula not only in the 1990s but also in the 2000s; right?
A. The early 2000s I believe is correct.

Q. Is one of the base -- one of the -- is some of the data taken from the FDA survey? Do you know anything about that?
A. Just a little bit. Yes, I think that it's compatible with what was in the FDA survey.
Q. So your assumption, if I understand this, is that if she had E. sak she had E. sak at the same level as they were finding E. sak in the 1990s and early 2000s; right?
A. First of all, I don't believe there was any E. sak whatsoever, but for purposes of trying to do a calculation, I relied upon the historical concentrations of the very low numbers of less than one colony forming unit per hundred grams of powdered infant formula.
Q. In your testimony if I remember right you made the assumption that Jeanine was off-the-wall crying beginning at 4 a.m. that morning.
A. I didn't make the assumption. That's what was testified to I believe, really, really off-the-wall whining.
Q. Right. You were read a portion of the deposition that said -- where Megan Surber testified that then the 4:00 is when she started getting really, really off-the-wall whiney. That's what you were read.
A. Yes.
Q. And --
A. That's what I read, yes.
Q. That's where the reading by the defense stopped; correct?

A. This morning? Yes. I'm sorry.
Q. But that isn't where Ms. Surber stopped in her explanation; correct?
A. I don't recall.
Q. Well, you -- I mean, you based your opinion as to what happened on her deposition.
A. Certainly. There's no doubt the baby was very irritable and crying and off-the-wall activity. I mean, it's very clearly stated.
Q. Okay. Here's page 294 from her deposition. And when she answered the question, she said then the 4:00 is when she started really, really off-the-wall whining between 4 and 9 in the morning. That's the full answer she gave; correct?
A. Yes.
Q. And apparently are you just interpreting that as the really off-the-wall whining started at 4:00 and ignoring her comment to the effect that it -- of 4 to 9? Is that your assumption?
A. The way any -- the way any person would read this, it says and then the 4:00 is when she started getting really, really-off-the-wall whiney, between 4 and 9 in the morning of the 24th. To me that means it started around 4:00 and it continued until 9 in the morning. Now, I don't know that anyone else would read that differently.
Q. Well, are you suggesting the baby started wh -- or quit whining at 9:00?

A. No, but she's speaking of --
Q. In fact --
A. She's speaking of that time period.
Q. Wait a second. That was a yes or no; okay? No. You know that she did not stop whining at 9:00 but, in fact, whined and cried and carried on all day long; correct?
A. That's what I understand. She was irritable all day long.
Q. So when she said four to nine, she couldn't possibly have been giving you the times when the baby was whining because, in fact, they continued; correct?
A. That's not the way I would interpret this, no, sir.
Q. Okay. And that's fine. You're entitled to your interpretation.
A. Thank you.
THE COURT: Was that a question?
MR. RATHKE: No, Your Honor. I withdraw it.
Q. Now, as to the boiling of the formula, are you suggesting that the only time that she boiled the formula after it was reconstituted was at 9:00 in the evening?
A. I think I recall that she stated later -- with her later feedings that night she also boiled the formula.
Q. All right. Do you recall her stating in her deposition -- and I appreciate you weren't here the other day last week when she testified. But you recall in her deposition she said that she warmed the bottles that she took out of the refrigerator at

midnight and 4 a.m. Is that --
A. I think that's correct as far as I know.
Q. All right. And since at 9 p.m. she was just making the formula, she would have no reason to warm it, would she?
A. Well, she was feeding the baby at 9 p.m. also, so she was -- would be warming that portion of what she prepared.
Q. Well, okay. Let's talk about Troy for a moment. A page that was mentioned from his medical record which is Exhibit -- I'm sorry, 1005B. Highlight this, Pat. Now, it says meningitis was effectively ruled out as far as resolution of the patient's symptoms and chest X-rays was obtained to further monitor for pneumonia though the chest X-ray was negative, and it kind of goes on. But you see where it says that the meningitis was affectively ruled out for Troy; correct?
A. Correct.
Q. And you concur with that.
A. Yes, I'm sure that he didn't have meningitis, yes. He had pneumonia.
Q. In fact, you believe, do you not, that it is unlikely that he was the source of any cronobacter infection; correct?
A. Correct. I don't think he was the source, but I think he and the baby might have had a common source, but it's hard to know since we don't have a culture from him to prove that he had cronobacter.
Q. But you've stated that it is unlikely that he was a source.

A. I think I said it was unlikely that he was the source. Isn't that correct?
Q. You're right.
A. Thank you.
Q. So in other words, the source could have been Jeanine, and he (sic) could have gotten something from Troy?
A. Say that again. I'm sorry.
Q. I withdraw the question.
Now, there's a list -- do you have your report in front of you?
A. I do.
Q. All right. Why don't you turn to page 10. And I think you'll find that there is a list of about 23 different sources that you contend could have been the source of Jeanine's E. sak infection. Do you see that?
A. Yes, I think there's 21 listed there.
Q. 21. The first one is the St. Luke's Hospital environment.
A. Yes.
Q. Is there any evidence anywhere -- and you're a hospital epidemiologist, so you'd be the one to ask. Is there any evidence anywhere that anything that happened at the birth hospital during her birth admission would be a source for cronobacter?
A. There's nothing that specifically points to that, but if one is making a list of the possibilities in her environment --

this is where she spent the first two and a half or three days of her life -- it's a possibility that she might have acquired the organism in the hospital.

Q. But there's no evidence, is there?

A. There's no direct evidence.

Q. There's no circumstantial evidence either.

A. There's really no ev -- there's no evidence, but there's been, you know, no -- no testing of any kind was done to help evaluate that possibility.

Q. You did review the birth records for Jeanine.

A. I did.

Q. And James.

A. And James.

Q. And the delivery records for Megan. She was at the hospital the same time.

A. I don't recall reviewing the birth -- the mother's birth records, but I may have. I just don't recall that.

Q. Then you -- the next two you cite, the single-use bottles and the ready-to-feed, but those are commercially sterile; correct?

A. Well, they're packaged and commercially sterile, but the nipples need to be handled when you're putting them on to the two-ounce bottles, so if the hands are contaminated for whatever reason, there's a potential for contamination of the nipple as it's being applied to the bottle. So yes, they come

commercially sterile initially.
Q. All right.
A. But they need to be handled. That's the problem.
Q. Well, of course, they need to be handled so they can be opened and used.
A. Correct.
Q. Everyone that uses it has to handle it.
A. That's correct. That's why good hand washing and hygiene is really important.
Q. Did you see any evidence in Megan Surber's deposition that she did not follow good hygiene?
A. There was nothing mentioned in her deposition to suggest that, but we never know.
Q. You never know.
A. Correct.
Q. That's kind of where you're coming from, we never know; correct?
MS. GHEZZI: Objection, Your Honor. Argumentative.
THE COURT: Overruled.
BY MR. RATHKE:
Q. The refrigerator, okay, so what would be refrigerated would be the ready-to-feed. That's the only thing that would need refrigerating after it was opened; correct?
A. That's correct.
Q. And there might be some broccoli in the refrigerator.

A. Correct.
Q. So the hypothesis here is what? The cronobacter jumps from the broccoli to the bottle?
A. Of course not.
Q. The hypothesis is the mom messes with the broccoli and then opens the bottle?
A. The possibility exists -- it's not extremely likely. The possibility exists that if formula bottles are on the same shelf with the kinds of foods that can be contaminated that there can be cross-contamination by touching one item and then touching the second item or the second -- or the second item being the formula bottles could be contaminated by sitting on a rack that yesterday had meat or some other food stuff sitting on it so that you get cross-contamination. That's the only point.
Q. Was there any evidence of that type of cross-contamination?
A. In science? Absolutely.
Q. In this case.
A. Well, there's no testimony that bears on that.
Q. Well, there's testimony that Megan Surber washed her hands every time she made formula; right?
A. I think that's correct.
Q. Now -- and there's no testimony that she washed her hands, then went in the refrigerator and messed around with the salami, and then touched the powdered -- or the ready-to-feed; correct?
A. There's no testimony to that effect.

Q. The next several are the bottles, the nipples, the cabinet where the bottles were, anyplace -- whole b -- the bottle brush, the dish soap bottle. All those relate to the bottle. Isn't it a fact, however, that Megan before any bottle was used she boiled all of the bottles; right?
A. That's -- before their first use is what I understand, that's correct.
Q. Okay. And then as she would -- when she would use a bottle for a particular feeding, she would take it out of the cabinet and then she'd boil it again. That's what she testified to; correct?
A. I don't recall that specific testimony that she boiled them again. She certainly boiled them before the initial use.
Q. Well, if she boiled the bottle, the individual bottle that she was going to use to feed Jeanine, if she boiled that again separately, it would kill any germs that would be in the universe that might be on the bottle; correct?
A. Should do a good job of that.
Q. All right. And you understand that she boiled the water that she added to the formula; right?
A. Correct.
Q. Okay. Whatever happens to Sioux City water prior to it coming out of the faucet, that problem as far as the water in the formula was concerned -- is concerned with, that problem was resolved by her boiling the water before she reconstituted the

formula; correct?
A. That's correct with respect to the water that went in to mix up with the powder, yes.
Q. So the only water that she could have had contact with that wasn't boiled would be the bath water.
A. Well, no. There's water that pools around sinks and drains and faucets that splash around sinks.
Q. Jeanine's ten years -- ten days old. How is she going to have contact with that water?
A. I'm sorry. I'm sorry. I interpreted your question to mean the mother's contact. The mother's hands could have contact with all kinds of water that's around the sink that can contaminate the outside of the bottles and the nipples.
Q. Well, it'd be city water; correct?
A. I think -- I think they're on city water, yes.
Q. Do you have any reason to doubt the sanitariness of the -- that the city of Sioux City provides for its residents?
A. I've seen some information about chlorine levels and free chlorine levels, but I'm not an expert in water supplies like that.
Q. And then, of course, you talked about the different family members that would have had contact with this baby; right?
A. Yes.
Q. Now, if you add up all of the places that this baby had -- has been and all of the things that -- the way she was fed and

the people that had contact with her, there is absolutely nothing unusual about Jeanine's contacts with things and people during the time that -- until she got sick; correct?

A. There's nothing terribly unusual, no, although the issue of sewer back-up, mold, moldy wall that needed to be torn out, all that sort of stuff is an environment where bacteria really thrive so --

Q. Well, mold forms within walls; correct?

A. Excuse me. And I'm concerned about the storage of the formula on the floor under the crib. But I don't know for a fact that that's a pr -- that that's an etiology of this infection, but I'm very concerned about that as a possibility.

Q. If there was mold growing in that house in April 2008, it certainly would not be the only house that babies and mold would be in the same place at the same time; correct?

A. I think that's correct.

Q. If you take all -- you know, you got this list of 21 things. You -- you -- couldn't possibly be powdered infant formula, so let's look at these 21 things. Who do you nominate as number one?

A. Oh, I don't know. I told you I'm concerned about the storage of the formula, where it was stored. I'm concerned about the water and the potential for splashes and hand contact and dealing with the bottles and nipples and screwing the tops on and all that. Those would be my concern -- major concerns.

Q. Well, okay. So is that like your top one, two, or three?
A. I can't enumerate them. Sorry.
Q. James -- you're aware that when James came home from the hospital on April 24 he lived in that same house.
A. Correct.
Q. Presumably was subjected to the same bathing in the same place and the same feeding, although none of it was powdered infant formula, same relatives; correct?
A. I have no reason to doubt that.
Q. In fact, there isn't one single thing about James that's different than Jeanine except James didn't have any powdered infant formula; correct?
A. No, that's not correct. James wasn't in the household during the dates that Jeanine was prior to her developing her infection.
Q. So you're suggesting --
A. And there may have been issues with the water supply during that time and when he was not there, so that's all I can say about that.
Q. So you're suggesting if there's any cronobacter in the house on April 23 it all left on April 24?
A. No, I don't think I said that.
Q. James didn't get sick, did he?
A. Not with this particular organism, and that happens in my clinical experience all the time where one child --

Q. I didn't --
A. -- in the family gets sick, the other kids don't, the twin doesn't. We don't understand why that can happen with one of a series of children becoming sick with a particular infection when they all should have theoretically been exposed, but that happens all the time.
Q. Sure this isn't kind of a cohort study all by itself? You got two babies, practically everything is in common, same mom, same birth hospital, we can go on and on. Only one difference, powdered infant formula, one gets sick and the other doesn't. Cohort study?
A. No, sir.
Q. If babies could get sick from the broccoli and from this and from that and from some sewer -- you know, some leaking in the basement and the mold within the walls and God knows what, why aren't more babies getting sick?
A. We don't know that. It's a good thing that they're not, but we don't know why that is.
Q. And as I understand it, the only way that you would be satisfied that the powdered infant formula is the cause of her illness, the only thing that would satisfy you, is if they found cronobacter in a sealed can of powdered infant formula and it was a genetic match between the cronobacter in the can and that in the baby.
A. That would be the best supporting evidence, certainly.

Q. Well, in fact, you regard that as the only way that you would attribute cause to the powdered infant formula; correct?
A. That's the most secure way I would feel comfortable concluding that they're related, yes, from a scientific standpoint, yes, sir.
Q. Well, at your deposition you testified that that's the only way we could prove causation; correct?
A. That's -- from a scientific standpoint, that's absolutely correct.
Q. Even if -- let's -- let's assume -- and, of course, they collected the isolate from Jeanine, but they had nothing to compare it to. Let's -- what if Abbott when it got a positive test in its factory on January 8, the same day that the formula that Jeanine consumed was made, what if they had saved that isolate and it was compared to Jeanine's and found to be an identical genetic match? Would that convince you?
A. I'm not aware that there's any isolate that was ever confirmed to be cronobacter sakazakii at that time from the plant.
Q. Well, somewhere along the line there's some documents that say they took a test and found it to be positive for E. sak, so just bear with me. Let's say that they had --
MS. GHEZZI: Your Honor, that's testimony. Can we strike that, please? Motion to strike.
THE COURT: Well, I think he was trying to formulate a

question but . . .

MS. GHEZZI: He might have been, but I don't think that was it.

THE COURT: Well, I think he was. I'll go ahead and strike it. Start over again and try and form a question.

BY MR. RATHKE:

Q. Assume for the purpose of my question that E. sak was identified in the plant on the same day that this batch was manufactured. Just assume that. Would you be satisfied if that E. sak found in the factory was a genetic match to the E. sak found in Jeanine?

A. I would expect that if it was related there would be some evidence from the powdered infant formula itself that should be readily discernible. And you haven't said that that's the case.

Q. Okay. I'm not understanding. If E. sak from the factory matched E. sak in Jeanine, would you then be satisfied that the E. sak within the can of powdered infant formula was the cause of her illness?

A. No, I would not. I would be suspicious. I would want to do further investigation, and that further investigation would be to study -- would be to try to isolate the organism from cans produced at that time.

Q. Of course, as you may know, that investigation cannot occur because Abbott did not keep the isolate.

MS. GHEZZI: Objection, Your Honor. Lack of

foundation, and he's testifying.

THE COURT: Well, I think he was trying to formulate a question but . . .

BY MR. RATHKE:

Q. That kind of testing could not occur unless Abbott kept the isolate.

A. And unless there was an isolate which I have seen no evidence that there's such an isolate.

MR. RATHKE: I have nothing further.

THE COURT: Redirect?

MS. GHEZZI: Just briefly, Your Honor.

THE COURT: Why don't I give everybody an opportunity, including Dr. Shulman, for a stretch break.

Thank you. Please be seated. Thank you.

MS. GHEZZI: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MS. GHEZZI:

Q. Dr. Shulman, was Jeanine Kunkel's E. sakazakii isolate ever typed for a sequence type?

A. No, it was not.

Q. So does anybody know what sequence type her isolate is?

A. Not to my knowledge, no.

Q. Okay. And is this a case where there's been any epidemiological proof, microbiological proof, linking Abbott's powdered infant formula with Jeanine Kunkel's E. sak bacteria?

MR. RATHKE: Object to leading.

THE COURT: Sustained.

MS. GHEZZI: Your Honor, it's only l -- if his answer is yes. If the answer is no, it can't be leading.

THE COURT: That's not true.

BY MS. GHEZZI:

Q. Is there any -- is there any evidence in this case of any microbiological or epidemiological proof linking Abbott's powdered infant formula with Jeanine Kunkel's bacteria?

A. No.

MR. RATHKE: Object to leading.

THE COURT: Sustained. Rephrase it.

Q. Have you seen any epidemiological proof in this case linking Jeanine Kunkel's bacteria with Abbott's powder?

A. No, I have not.

Q. Have you seen any microbiological evidence in this case linking Jeanine Kunkel's b -- microbiological evidence linking Jeanine Kunkel's bacteria with Abbott's product?

A. No.

Q. In your experience is the mother in the family the only one who goes in and out of a refrigerator?

A. No. Of course not. Many people likely go in and out of the refrigerator in virtually any household.

Q. And are eight-year-old children likely to go in and out of a refrigerator in a home?

A. That's certainly my experience.
Q. And in terms of the twin brother James, is it your understanding that he didn't go back to the -- he did not get released from the neonatal intensive care unit until the day that Jeanine went to Omaha to the Children's Hospital in Nebraska?
A. I believe that's correct, or maybe the day before like -- or the same day, the same day I think. Yes.
Q. And do you have a recollection in the -- from the Megan Surber deposition testimony that she and her husband then stayed in Omaha with Jeanine while she was in the hospital for the next two months?
A. Yes.
Q. Okay. So James would not have been around his father Troy Kunkel during that time; correct?
A. Correct.
Q. And in -- counsel read you some portion of the Megan Surber deposition, and I just want to call your attention to a portion of this on page 314 concerning how she washed bottles when she fed the ready-to-feed in the 32-ounce jar which I believe is referred to in your report, and it says, so how would you wash the bottles? Answer, hot water, soap after use. Do you recall that?
A. Yes.
Q. Okay. And counsel also referred you to the 2008 World

Health Organization report. Do you recall that?
A. Yes.
Q. And you reviewed that report at the time of your report.
A. Yes.
Q. And do you recall where it said from a U.S. survey that more than half of the caregivers, 55 percent who were surveyed, said that they did not always wash their hands before preparing infant formula and about 4 to 6 percent of caregivers said they sometimes use bottle nipples again without cleaning them in any way and about a third of caregivers sometimes only rinsed bottle nipples with water between uses? Do you remember that?
A. Yes.
Q. Okay. Now, if that had happened in this case, what would you expect with respect to the bacteria load on the nipples and the bottles used in the ready-to-feed feedings?
A. The concentration of the germs on the nipples and bottles would gradually increase with the doubling time as would be appropriate for the temperature they're at and could lead to a very high concentration of contamination of -- with this enterobacter sakazakii.
Q. Okay. Now, doctor, in medical microbiology, do you sometimes get preliminary -- what are called preliminary positive results when you test a culture?
A. Yes. I'm the medical director of the microbiology laboratory, and not a day goes by that we don't have a

preliminary report that we send out that needs to be then finalized.

Q. And is it standard medical microbiological practice to do further testing on a preliminary positive result of a culture to confirm whether or not it is a real positive or not?

A. Yes. I mean, that's the whole purpose is to send a preliminary report out pending doing further testing to confirm whether the report is confirmed or is erroneous.

Q. And does it happen on occasion or many occasions where those preliminary positive results end up being negative?

A. Yes, it does. Probably 50 percent of the time they wind up being not what the laboratory initially thought it was.

MS. GHEZZI: Okay. No further questions. Thank you, Your Honor.

THE COURT: Thank you. Any recross?

MR. RATHKE: Yes, Your Honor.

RECROSS-EXAMINATION

BY MR. RATHKE:

Q. Kevin, he was eight years old at the time?

A. I'm sorry?

Q. Kevin, he was eight years old at the time?

A. Yes.

Q. Are you suggesting that he might have gone into the refrigerator, messed with the broccoli, and then drank some of the powdered infant formula?

A. No, sir. He may have touched the bottles.
Q. Why would he do that?
A. Because he's eight years old. I mean, it's a possibility. I mean --
Q. He's touching the baby's formula?
A. It's novel to him, so he might well want to do that. Who knows?
Q. The fact is also that James -- James came home the very day that Jeanine was first hospitalized at St. Luke's Hospital; correct? I think the hospital records will verify that James was released on the 24th and June -- or Jeanine was hospitalized on the 24th.
A. That is correct.
Q. All right.
A. Both of those pieces of information are correct.
Q. Are you familiar -- counsel asked you some questions about microbiological testing. Are you familiar with the Bar decision? Have you ever heard that before?
A. The Bar decision?
Q. Yeah, I'm just asking you if you ever heard of it.
A. I don't think so.
Q. Have you ever heard of the concept that you can't test your way out of a negative or you can't test your way into compliance?
A. I don't have any idea what you're talking about.

Q. Would you agree with the proposition that if you have a positive for something that you don't -- you don't want to have a positive, it's a bad thing, and then you do a second test and it's a negative that the negative doesn't trump the positive unless there's a very good scientific basis to do so? Does any of that ring a bell?
A. Sure. That rings a bell. But what I understand is going on here for the preliminary report is that it's not a new specimen that is being obtained to run the test again. The preliminary report is based upon the original specimen, and then further testing is performed on that very same specimen to try to confirm or not the presence of a particular germ.
Q. Did you review the Abbott records relating to the microbiological testing of that environmental sample?
A. I think I only reviewed the report.
Q. So you don't know what happened with that, do you?
A. Well, I know what a preliminary report means, and a preliminary report needs to be confirmed by additional -- and I think the report -- preliminary report actually even says it's going to be further evaluated by additional technology.
Q. Do you have any idea what kind of testing was done on the second round of tests?
A. Some kind of molecular assay. I know that.
Q. Is that as far as I can take you on that?
A. Yes.

Q. Counsel mentioned a survey of moms, and I think the point was that a lot of moms aren't washing their hands and stuff?
A. Correct.
Q. My question on that is then why aren't babies getting sick with cronobacter infections?
A. Well, they're lucky. Fortunately they're not getting sick. That's a good thing.
Q. And is it your test -- is it your belief that Megan simply washed the bottles before she used them and that she did not sterilize the individual bottle before she used it?
A. My understanding is that the first time she used the bottles she sterilized them but she did not repeatedly sterilize them after their initial sterilization and usage. She washed them in hot, soapy water from the tap.
Q. All right. Here's page 327 from her transcript. I'm asking her -- or counsel for Abbott is asking her questions, and she's answered them, and I've underlined some things. Isn't she saying that every time she used a bottle she boiled it first?
MS. GHEZZI: Your Honor, I would just object that in the -- it's not clear from the context of this one page or several pages what it is they're talking about in terms of which feedings, if he can point it out to him.
THE COURT: And so what is the nature of that objection? I haven't ever heard that one before.
MS. GHEZZI: It's confusing.

THE COURT: Well, it may be confusing to you, but he didn't ask the question to you. He asked it of the witness.

MS. GHEZZI: Okay. Might be confusing to the witness.

THE COURT: Yeah, that's suggesting an answer which is exactly the problem I had with your depositions.

MS. GHEZZI: I would just object to the form of the question then, Your Honor.

THE COURT: That's not a proper objection, so it's overruled.

A. As I read this, I can't be certain as to what exactly she's referring to at what point here.

Q. All right. Here's the question.

THE COURT: Just a second. I want to see the lawyers at sidebar.

(At sidebar on the record.)

THE COURT: Don't you ever do that again, or I'm going to sanction you right in front of the jury. That's exactly the problem with your deposition conduct. You suggested an evasive answer for the witness by making your speaking objection which I told you at the beginning is not allowed, and then he just followed up and said, well, yeah, it's confusing, I can't answer that. And that's improper.

MS. GHEZZI: Your Honor, my objection was object to the form. It was confusing. And it is because --

THE COURT: It's confusing to you.

MS. GHEZZI: No, no, it's confusing because you can't tell what this is.

THE COURT: You did not object to the form until the very end, and I'm going to file a published opinion saying that's not a proper objection because it isn't in my view. You gave a speaking objection. I don't even know what the objection was. Finally when I asked you you said it was confusing. You were educating him as to how to answer it by saying it was vague. The lawyer didn't ask you the question. He asked the witness. It's totally improper. And if you do it again, there will be heck to pay for it.

(The sidebar was concluded.)

THE COURT: Mr. Rathke, you may proceed.

MR. RATHKE: Thank you, Your Honor.

BY MR. RATHKE:

Q. I only have the one copy, but after I'm through reading if you want to look at it again, feel free. Question was, so do you -- how long would this process take from getting ready with the bottle to when you were feeding her? Answer, half hour maybe. I would get the bottle, sterilize it first, then put it in, and then boil -- put the bottle in boiled water or warm it up I should say.

Does that suggest to you that she boiled the individual bottle before she used it?

A. It suggests at some point she boiled the -- boiled the

water -- boiled the bottles, but it isn't completely clear as to when exactly that refers to.

Q. All right. And another question on the next page, 328, okay, and when you said you would boil the bottles, was that because they were sitting up in the cabinet for a while? And her answer was yeah. So they're sitting there, and you always want to sterilize them before you use them.

Doesn't that tell you that after she took an individual bottle out of the cabinet that she would sterilize it?

A. That sounds like that, yes.

MR. RATHKE: Okay. Thank you. Nothing further.

THE COURT: Any redirect, re-redirect?

MS. GHEZZI: Just a couple of questions, Your Honor.

THE COURT: Thank you.

FURTHER REDIRECT EXAMINATION

BY MS. GHEZZI:

Q. Dr. Shulman, was Kevin, the half brother, ever tested for E. sak?

A. No.

Q. And was the refrigerator ever tested for E. sak?

A. No.

Q. And were the contents of the refrigerator ever tested for E. sak?

A. No.

Q. And was the door handle of the refrigerator ever tested for E. sak?
A. No.
Q. And were any of the extended family ever tested for E. sak?
A. No.
Q. And was Megan Surber ever tested for E. sak?
A. No.
THE COURT: Those are all leading. They're all stricken. Jury's admonished to disregard all of the answers that the witness has given.
You can now do whatever re-redirect you want, but you can't ask a leading question.
BY MS. GHEZZI:
Q. Was anybody in the home -- was anybody in the home tested for E. sak?
A. No.
MS. GHEZZI: Thank you, Your Honor. No further questions.
THE COURT: Anything further?
MR. RATHKE: No, Your Honor.
THE COURT: Okay. You may step down.
THE WITNESS: Thank you, Your Honor.
THE COURT: Thank you.
MR. RATHKE: Questions from --
THE COURT: Oh, I'm sorry. Yes. We're going to see

if we have any questions from the jury. I'm sorry. Thank you for reminding me. Are there any juror questions? Doesn't look like it.

Thank you, though, Mr. Rathke.

You may step down.

MS. GHEZZI: It's Dr. Shulman.

THE COURT: I was thanking Mr. Rathke --

MS. GHEZZI: Oh, I'm sorry.

THE COURT: -- for pointing out that I forgot to ask the questions.

MS. GHEZZI: Oh, I'm sorry, Your Honor.

THE COURT: No, that's okay.

MS. GHEZZI: I can barely see.

THE COURT: No, no, no, that's okay. Don't worry. You thought I was talking about the witness, and I was talking to counsel, so no problem.

Do you have another witness we could at least get started on, or would you --

MR. REIDY: Your Honor, I think rather than start a relatively long witness, we do have a transcript we could start to read.

THE COURT: Okay. That's fine. Are you ready to go with that?

MR. REIDY: It might be stretch breakable, but then we'll be ready to go.

THE COURT: Okay. Why doesn't -- thank you. Why doesn't everybody take a stretch break.

Thank you. Please be seated.

MR. SCANNAPIECO: Your Honor, our next witness is Russell Merritt by deposition.

THE COURT: Okay. And is Mr. Gray going to be reading that?

MR. SCANNAPIECO: He'll be reading Russ Merritt.

THE COURT: Yeah.

MR. SCANNAPIECO: I will be reading Mr. Rathke, the role of Mr. Rathke.

THE COURT: Okay.

MR. RATHKE: I'd read my own if -- that's fine.

(Deposition designations of Russell Merritt were read in open court.)

THE COURT: Mr. Scannapieco, is now a good time to take our break for the day?

MR. SCANNAPIECO: I believe it is, Your Honor.

THE COURT: Okay. Why don't you mark the place where you're at so you'll know where to start up again.

Members of the jury, that concludes the testimony for today. Keep an open mind until you've heard all of the evidence, and we'll see you back here tomorrow at 8:30. Thank you.

(The jury exited the courtroom.)

THE COURT: Okay. Please be seated. I want to clarify a couple of things. You know, I've been a lawyer for 39 years. I've never in my life heard that a leading question is not leading because it suggests a no answer rather than a yes answer. And I suspect you can search the entire universe of federal and state cases and never find a court that agrees with that.

And, you know, the problem -- well, you asked nothing but leading questions in that whole series which I struck. But with regard to your objection, if you want to object to the form of the question, that's fine. That's actually not what the rules say. The rules say any objection not made to a form of the question is waived. It doesn't say the form of the question is a proper objection.

And in my view -- and I know there are courts that disagree with me because I'm very familiar with the law in the area. There are a number of courts that say object to form is a proper objection. The reason why it's not is there are at least nine known subparts of what that might mean, and it doesn't put the opposing lawyer in a deposition or a judge on notice as to what the objection is.

But that's not why I was upset with you. I was upset with you because you went on and on with a speaking objection that coached the witness that you thought the question was too vague and that he should think it was too vague. That's exactly

what your speaking objection did, and that's absolutely impermissible. And that's what you repeatedly do in depositions.

This is the -- you're a very, very fine trial lawyer. And this is the first time you did it with a witness, but then this is -- you know, we're just getting started in the defense case. But you cannot give a speaking objection about how vague and you don't understand it and all and then the witness parrots the exact same thing, oh, yeah, I think it's vague and just parrots what you said.

MS. GHEZZI: I understand, Your Honor.

THE COURT: That's impermissible.

MS. GHEZZI: I understand, Your Honor. I was just -- I was just trying to explain what the basis of it was. That was all I was trying to do. I was not trying to coach the witness. I was just trying to explain so Your Honor would understand why I was making objection to the form.

THE COURT: How about this? It's vague.

MS. GHEZZI: That's a good one.

THE COURT: Form doesn't mean anything to me at all because form can be it's leading, it's compound, it's complex, it's -- I mean, I think when I've researched this I found nine different subject matters that come within permissible objections to the form. But saying I object to the form is just like saying I object because it violates the rules of evidence.

Yeah, really it might, but which rule? Is it a hearsay objection? Is it a leading objection? Is it a foundation objection? It doesn't tell the person anything.

So -- but I understand most courts disagree with me and say objection to the form is fine. But for the reasons I've just articulated, I don't -- that's not a problem.

But I guarantee you on your leading question, matter of fact, if you look at Black's Law Dictionary which I just did, basically it says a leading question is one that contains a material fact that suggests the answer which could be either yes or no. And that's exactly what all your questions were in my view. That's all. You're free to disagree, but I thought they were extremely leading. And you're in great company because 99 percent of all lawyers including all of the lawyers on the other table do nothing but leading questions on redirect. They asked virtually nothing but leading questions on redirect.

MS. GHEZZI: Right.

THE COURT: But yours was just such a strain. So anyway, anything we need to take up for tomorrow?

MR. RATHKE: No, Your Honor.

MS. GHEZZI: No, Your Honor.

THE COURT: Are we on track witnesswise?

MS. GHEZZI: We are.

THE COURT: Okay.

MS. GHEZZI: We are. Thank you.

THE COURT: And it looks like -- just so you know, I mean, I hate to encourage you to spend -- to slow down your case, but we just got an e-mail that my patent case starting next Tuesday is like -- the parties have said it's likely to settle which I've kind of thought all along so . . .

MR. RATHKE: Does that mean I have to spend another weekend in Sioux City?

THE COURT: Really. Well, you know, we can use all of next week for your rebuttal case.

MR. REIDY: Judge, I think that we will still finish our case this week, and I'm very hopeful we can argue the case this week.

THE COURT: Oh, you think we'll be able to argue it on Friday?

MR. RATHKE: Thursday.

MR. REIDY: Yeah, I think we'll be able to argue it on Friday for sure, possibly even Th -- we're still talking, giving hints as to how we might narrow our case even more.

THE COURT: Okay. Great. Appreciate it.

MR. REIDY: That's our goal.

THE COURT: Okay. Thank you. We'll be in recess.

(The foregoing trial was adjourned at 2:37 p.m.)

CERTIFICATE

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

S/Shelly Semmler
Shelly Semmler, RMR, CRR

9-5-14
Date

INDEX

WITNESS:		**PAGE:**
BRAD PUETZ		
	MS. VAN WYHE	931
	MR. SCANNAPIECO	935
LOUISE DEITLOFF		
	MS. VAN WYHE	945
	MR. REIDY	947
PAMELA ANDERSON		
	deposition	949
LARRY WILLIAMS		
	deposition	949
STANFORD SHULMAN		
	MS. GHEZZI	955
	MR. RATHKE	1005
	MS. GHEZZI	1043
	MR. RATHKE	1047
	MS. GHEZZI	1053
RUSSELL MERRITT		
	deposition	1056

*****